

# Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages

OMB No. 0910-NEW

## SUPPORTING STATEMENT

### Part A

#### A. Justification

##### 1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) has the responsibility to protect public health by assuring the safety and security of our nation's food supply and by assuring that foods are effectively labeled. In addition, the FDA is responsible for advancing public health by helping the public to get the accurate, science-based information they need to use foods to improve health.

FDA conducts research and educational and public information programs relating to food safety pursuant to its broad statutory authority, set forth in section 903(b) (2) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 393 (b)(2)), to protect the public health by ensuring that foods are "safe, wholesome, sanitary, and properly labeled," and in section 903(d)(2)(C) (21 U.S.C. 393 (d)(2)(C)), to conduct research relating to foods, drugs, cosmetics and devices in carrying out the act. As a public health agency, FDA helps consumers make informed dietary decisions by regulating nutrition information in food labeling, initiating its own consumer education activities, and collaborating with public and private entities in conveying nutrition information to consumers. These activities are aimed at influencing consumer awareness, understanding, and behaviors related to diet and nutrition and ultimately health outcomes of the Nation.

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 suggests half of the grains consumed should be nutrient-dense whole grains (Ref. 4). At the same time, whole grain claims 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 the whole-grain claims. Several studies indicate that consumers may have difficulties in understanding the meaning of whole grains or recognizing whole-grain foods (Refs. 6 through 8). For example, many consumers assume that the health benefits of whole grains primarily lie in fiber (Ref. 9). Studies by Kellogg showed that some consumers may understand whole grain statements as implied nutrient content claims for fiber even though these statements do not follow the same standards for nutrient content claims and thus may not provide much fiber at all (Ref. 12). On the other hand, the benefits of whole grains go beyond fiber. For example, consumers may not realize that foods such as brown rice is a whole grain food and can provide nutrients and minerals such as iron, selenium and magnesium besides fiber (Ref. 4). Research also suggests consumer product perceptions and purchase decisions can be influenced by labeling statements and different labeling statements may have different influences (Refs. 10 and 11).

FDA is proposing to conduct an experimental study to quantitatively assess consumer reactions to different whole grain statements. The purpose of the study is to help enhance FDA's understanding of consumer comprehension and perceptions of food labels that use whole grains labeling statements. The study is part of the agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets. The results of the study will be used for informing possible measures that the agency may take to help consumers make such choices.

## 2. Purpose and Use of the Information Collection

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. This study is intended to provide answers to research questions such as whether consumers understand the differences between whole grain and fiber, how they understand the claims such as "Whole Wheat," "Multi-Grain" and "Made with Whole Grain," the benefits of and need for whole grains consumption, and the role that demographic and other factors may play in any individual differences. Specifically, the study will focus on (1) consumer ability to use certain whole grain claims to judge the amount of whole grain and fiber in the food product; (2) consumer judgments about a food product, based on the whole grain claim, in terms of its nutritional attributes and overall healthfulness; and (3) whether consumer can discern the differences between certain statements (e.g., "Made with Whole Grain" and "Whole Grain").

The study will use a completely randomized experimental design to statistically test differences in response to experimental stimuli, i.e., label images. The study will employ quantitative methodologies, such as descriptive and two-sample t statistics, analysis of covariance, and generalized linear model to compare and test response differences among 12 whole grain statements in terms of the amount of whole grain, the amount of fiber, healthiness or nutritional qualities of the product, after controlling for demographic and health variations between participants.

The study will randomly assign each of its 2,700 participants to view one label from a set of food labels that vary in whole grain statements, product category, nutritional profile and ingredient list. The study will employ a 12 (statement—11 claim statements and a no-claim control) x 3 (product category--bread, salty snacks, breakfast bars) x 2 (nutritional profile– one high in fiber amount; one low in fiber amount) x 2 (ingredient list--one has whole grain wheat listed in the first position and one has whole grain wheat listed in the sixth position) x 2 (availability of Nutrition Facts--by voluntary access, by default) design. Each respondent will be randomly assigned to one of the 288 conditions. We are intending to have a balanced cross-nested designs design with 9 respondents in each condition.

The study will use the experimental data to test the following null hypotheses:

Hypothesis 1: There is no difference between the twelve whole grain statements (including a no-claim control) in these dependent measures: (1) the amount of whole grain; (2) the amount of fiber; (3) product judgments (including taste, texture, and healthiness or nutritional qualities); (4) purchase intent; (5) perceived credibility and helpfulness of the statement.

Hypothesis 2: There is no difference between the three food categories in: (1) the amount of whole grain; (2) the amount of fiber; (3) product judgments; (4) purchase intent; (5) perceived credibility and helpfulness of the statement.

Hypothesis 3: There is no difference between the two nutrition profiles in: (1) the amount of whole grain; (2) the amount of fiber; (3) product judgments; (4) purchase intent; (5) perceived credibility and helpfulness of the statement.

Hypothesis 4: There is no difference between the two ingredient lists in: (1) the amount of whole grain; (2) the amount of fiber; (3) product judgments; (4) purchase intent; (5) perceived credibility and helpfulness of the statement.

Hypothesis 5: There are no interaction effects among whole grain statements,, food category, nutrition profile and ingredient list (including all six possible 2-way interactions) in any of the dependent measures.

### 3. Use of Improved Information Technology and Burden Reduction

The study will use web-based surveys. Web-based surveys not only reduce the burden on respondents, but also minimize possible administration errors and expedite the timeliness of data processing. Compared to face-to-face interviews and mailed surveys, web-based surveys are less intrusive and less costly.

The proposed information collection will recruit respondents and conduct experiments via the Internet. FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's request. The Internet mode of data collection is more appropriate than other modes, e.g., telephone or in-person, because of its advantages in respondent burden, cost, administration, speed, and absence of interviewer effects.

4. Efforts to Identify Duplication and Use of Similar Information

The agency concluded that the proposed data collection will not duplicate any similar study and the existing knowledge base and literature do not meet the agency's informational need.

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 statements. We are aware of at least one existing study related to whole-grain statements (Ref. 12). However, the study did not compare consumer reactions to various whole-grain claims.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this collection.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection. Without this study, FDA will not have the needed information to understand consumer responses to food labels that use whole grains labeling statements. The lack of understanding would impede the agency's ability to provide better information useful to consumers, which in turn can elevate the nutrition and health status of the general population.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

No special circumstances will occur in the data collection.

The collection fully complies with 5 CFR 1320.5(d) (2). There are no special circumstances associated with this information collection. The study will not require respondents to: report the information more often than quarterly; provide a written response in less than 30 days; submit more than one original plus two copies of the information; or retain records for more than 3 years. The design of the experimental study will not produce results that cannot be generalized to the response universe of study. The study will not use statistical data that has not yet been reviewed or approved by OMB. The study will not include a pledge of confidentiality that is (1) not supported by authority established in statute or

regulation; (2) not supported by disclosure and data security policies that are consistent with the pledge; or (3) which unnecessarily impedes sharing of data with other agencies for compatible confidential use. Finally, the study does not involve the submission of trade secrets, proprietary information or other confidential information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), in the Federal Register of March 26, 2011 (76 FR 30725), FDA published a 60-day notice requesting public comment on the proposed information collection. FDA received eight letters (including letters for request for extension of comment period) in response to the notice. The comments, and the agency's responses, are discussed in the following paragraphs. Some of the comments received were not responsive to the comment request on the four specified aspects of the collection of information. These non-responsive comments will not be addressed in this document.

(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 1) 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 trustworthiness, helpfulness of the whole grain statement may be biased or leading since 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 2) 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 (Ref. 13) has suggested that such a response can be interpreted as a “don’t know” response by some respondents. Therefore, we have kept the 6-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 mockup 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 3) 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 vs. 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 4) 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 5) 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 8g of whole grain”) into the study to see whether consumers can use them to seek out whole grains.

(Response 6) 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 7) 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 8) 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 9) 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, since 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 10) 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 11) 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% DV) for foods with a mid to large size RACC, such as those associated with ready-to-eat cereals.

(Response 12) 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.

9. Explanation of Any Payment or Gift to Respondents

We will recruit members on the Knowledge Networks' KnowledgePanel to participate in the study. Knowledge Networks (KN) provide non-specific survey incentives in order to maintain a high degree of panel loyalty and to prevent attrition from the panel. For the households that are provided Internet appliances and an Internet connection by KN, their 'panel loyalty' incentive is the hardware and Internet service that KN provides free. For households using their own personal computers and Internet service for survey participation, KN enrolls the panelists into a points program that is analogous to a 'frequent flyer' program, in that respondents are credited with points in proportion to their regular participation in surveys. Panelists receive cash-equivalent checks approximately every four to six months in amounts reflecting their level of participation in the panel, which commonly results in distributions in the range of \$4 to \$6 per month.

We plan to conduct nine cognitive interviews. Participants will be paid \$25 for a 30-minute interview. The use of incentives is a standard practice in data collection in general (see the American Association of Public Opinion Research Best Practices Guidelines at [http://www.aapor.org/Best\\_Practices1.htm#best9](http://www.aapor.org/Best_Practices1.htm#best9)). To ensure adequate participation and high data quality, we propose the above incentive amount. This amount was determined based on information provided by our contractor about the going rates offered to participants in the Washington, D.C. metropolitan area for interviews of similar type, scope, and length of time. The amount reflects the current cost of gas and other travel expenses. The amount also helps to ensure that participants are reasonably diverse in age, gender, and education.

10. Assurance of Confidentiality Provided to Respondents

All data will be collected with an assurance that the respondents' answers will remain confidential. The study instrument will contain a statement that responses will be kept confidential. Identifying information will not be included in the data files delivered by contractors to the agency. Information will be kept private to the extent permitted by law. ~~FDA will keep the study data confidential to the extent permitted by law.~~

Knowledge Networks, KN, the Agency's data collection contractor, will collect the study data and follow its standard confidentiality and privacy policy:

"Survey responses are confidential, with identifying information never revealed without respondent approval. When surveys are assigned to KnowledgePanel Members, they receive notice in their password protected e-mail account that the

survey is available for completion. Surveys are self-administered and accessible any time of day for a designated period. Participants can complete a survey only once. Members may leave the panel at any time, and receipt of the laptop and Internet service is not contingent on completion of any particular survey.

All KN panelists, when joining the panel, are given a copy of the Privacy and Term of Use Policy. The privacy terms are also available electronically at all times to panelists via the Panel Member website. The Privacy and Terms of Use Policy is posted at <http://www.knowledgenetworks.com/company/privacy.html>.”

In addition, all electronic data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

#### 11. Justification for Sensitive Questions

The study will ask respondents their height, weight, perceived health, perceived weight status, special diets, and status and risk perception of chronic illnesses. This information is needed for two purposes. First, we are interested in investigating how these personal characteristics affect respondents’ nutrition- and health-related perceptions, attitudes and behaviors. Second, in that personal characteristics may explain some of the variations in respondents’ perceptions, attitudes and behaviors, the study will examine these variations by controlling for personal characteristics.

The agency’s experience with these questions suggests that the overwhelming majority of respondents feel comfortable in providing this information. For example, in the Experimental Study of Health Claims on Food Packages (OMB Control No. 0910-0565), the item non-response rates due to refusal were <1% for height, perceived weight status, special diets, and status and risk perception of chronic illnesses. Only the question of weight received a non-response rate of 6%.

Despite the evidence above, the experimental study will put a sentence before asking health status questions that reads “the next few questions may seem a bit personal, but we need this information because this survey is about nutrition and health.” We have used this sentence in previous data collections.

#### 12. Estimates of Annualized Burden Hours and Costs

##### 12a. Annualized Hour Burden Estimate

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 one 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 published in the 60-day notice. The change is because we increased the number of our experimental conditions from 156 to 288 and we also 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 published 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<sup>1</sup>

Portion of Study	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Cognitive interview screener	72	1	72	0.083 (5 min.)	6
Cognitive interview	9	1	9	1	9
Pretest invitation	1,152	1	1,152	0.033 (2 min.)	38
Pretest	576	1	576	0.25 (15 min.)	144
Survey invitation	5,400	1	5,400	0.033 (2 min.)	180
Survey	2,700	1	2,700	0.25 (15 min.)	675
Total					1,052

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is \$17,116 (1,052 x \$16.27) at \$16.27 per hour (the 2010 median wage rate in the U.S.) See [http://www.bls.gov/oes/current/oes\\_nat.htm#00-0000](http://www.bls.gov/oes/current/oes_nat.htm#00-0000).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated total cost to the Federal Government for this information collection \$300,000. This includes the value of a task order to execute the collection of information and the value of a Full-Time-Employee to develop, monitor and analyze the data collection.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

We plan to complete data collection and analysis within two years from the date of OMB approval. The planned schedule for the project is shown in Table 2.

The purpose of tabulation is to quantitatively analyze the data and summarize findings to meet the informational needs. Commonly accepted statistical techniques such as descriptive analysis, analysis-of-variance (ANOVA), and generalized linear model will be used to analyze the experimental data.

Table 2. Project Schedule

<b>Date</b>	<b>Activity</b>
Within 1 day following OMB approval	Notification to contractor to proceed with data collection
Within 45 days following OMB approval	Completion of data
Within 75 days following OMB approval	Completion of data delivery by the contractor
Within 135 days following OMB approval	Completion of preliminary analyses
Within 180 days following OMB approval	Beginning of review, clearance, and dissemination of preliminary findings

FDA will disseminate the results of this study strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public." In describing the data collected and results of the analysis, FDA will clearly acknowledge that the experimental data does not provide nationally representative population estimates such as consumer attitudes, knowledge, or behaviors but

provides valid and quantitative estimates of differences across experimental conditions.

The dissemination may include internal briefings and reports, presentations and articles at trade and academic conferences, in professional journals, and posting on FDA Web site.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB approval and expiration date will be displayed on all materials associated with the study. No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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>.
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5. Supermarket News. Report: Whole Grains Gain Momentum. September 2010. Available at [http://supermarketnews.com/news/whole\\_grains\\_0917/#](http://supermarketnews.com/news/whole_grains_0917/#)
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