formulating policy for the privacy and security of health information; (5) developing policies as may be otherwise necessary for implementing its mission; and (6) maintaining a Federal Health IT Strategic Plan.

V. Under Part A, Chapter AR, Office of the National Coordinator for Health Information Technology, Section AR.20 Functions, Chapter E, delete, ''Office of Policy and Research (ARF),'' in its entirety and replace with the following:

E. *Office of the Deputy National Coordinator for Operations (ARE):* The Office of the Deputy National Coordinator for Operations is headed by the Deputy National Coordinator for Operations. The Office of the Deputy National Coordinator for Operations is responsible for performing the activities that support the Office of the National Coordinator for Health Information Technology's numerous programs. These include: (1) Budget formulation and execution; (2) contracts and grants management; (3) facilities management; (4) human resources; (5) stakeholder communications; and (6) financial and human capital strategic planning.

VI. Under Part A, Chapter AR, Office of the National Coordinator for Health Information Technology, Section AR.20 Functions, immediately following Chapter E, insert the following:

F. *Office of the Chief Privacy Officer (ARF):* The Office of the Chief Privacy Officer is headed by the Chief Privacy Officer, who advises the National Coordinator as directed by the ARRA. The Chief Privacy Officer may also report to other individuals, as necessary. The Chief Privacy Officer of the Office of the National Coordinator for Health Information Technology will be appointed by the Secretary. The Office of the Chief Privacy Officer is responsible for: (1) advising the National Coordinator on privacy, security, and data stewardship of electronic health information and (2) coordinating the Office of the National Coordinator for Health Information Technology's efforts with similar privacy officers in other Federal agencies, State and regional agencies, and foreign countries with regard to the privacy, security, and data stewardship of electronic, individually identifiable health information.

VII. *Delegation of Authority.* Pending further delegation, directives or orders by the Secretary or by the National Coordinator for Health Information Technology, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

Authority: 44 U.S.C. 3101.

Dated: November 20, 2009.

Kathleen Sebelius,

Secretary.

[FR Doc. E9–28755 Filed 11–30–09; 8:45 am]

BILLING CODE 4150–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0220]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Studies of Nutrition Symbols 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 (PRA).

DATES: Fax written comments on the collection of information by December 31, 2009.

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: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title ''Experimental Studies of Nutrition Symbols on Food Packages.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794, *Jonna.Capezzuto@fda.hhs.gov*.

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.

I. Experimental Studies of Nutrition Symbols on Food Packages

With the increased interest in healthier foods, U.S. food processors and retailers have been adding nutrition information, particularly nutrition quality icons (e.g., Smart Choices Program) and selected nutrient level disclosures (e.g., Guideline Daily Amounts), in addition to other labeling statements (e.g., nutrient content claims), to the front of the package (FOP). This type of nutrition labeling scheme is seen in other countries (e.g., United Kingdom, Sweden, and Australia) as well. FDA believes the proliferation of these nutrition labeling schemes in the domestic market and the various nutrition criteria they use make it necessary for the agency to exercise the responsibility that Congress gave it to, among other things, carefully examine consumer understanding and use of the various schemes to evaluate how well they impart useful nutrition information to U.S. consumers and which schemes or types of schemes are better to impart the information. The agency held a public hearing in September 2007 and completed a focus group study in April 2008 to obtain comments and information about many consumer issues related to FOP nutrition labeling schemes. We are also aware of recent consumer research conducted by foreign governments, non-governmental organizations, and academics (e.g., Refs. 1 to 4). The existing information, however, does not fill many of the gaps in our understanding of the impacts of FOP nutrition labeling schemes on U.S. consumers. Most importantly, there is a lack of publicly available quantitative consumer research on the relative effectiveness of existing and alternative labeling schemes in helping U.S. consumers make better dietary decisions. Therefore, the agency is proposing to conduct two experimental studies to assess quantitatively consumer reactions to various FOP nutrition labeling schemes. The studies will provide critical input to ensure the usefulness of FOP nutrition information provided to U.S. consumers.

FDA conducts research and educational and public information programs relating to food safety under its broad statutory authority, set forth in section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (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.

The purpose of the studies is to help enhance FDA's understanding of consumer understanding and use of a selected sample of nutrition labeling schemes currently in use in the domestic market, and to examine whether certain schemes are better ways to impart useful nutrition information to U.S. consumers. The studies are part of the agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets.

The experimental studies will be conducted by two different contractors using two different Web-based surveys to collect information. Study participants will come from two independent convenience samples of adult members recruited from two separate online consumer panels; the demographic characteristics of each sample will be matched to that of the respective consumer panel.

A. Study 1

Study 1 will examine five labeling conditions: (1) a Smart Choices Program scheme (currently used in the U.S. market); (2) a Guideline Daily Amounts scheme (currently used in the U.S. market); (3) a scheme similar to the Multiple Traffic Light, which is currently used in the United Kingdom; (4) a control that shows only the Nutrition Facts label; and (5) a control that shows no FOP nutrition information. The study will randomly assign each of its 2,400 participants to view four labels from a set of 40 FOP food labels that vary in the presence and type of labeling information, the type of food product, and the nutritional qualities of the product. The study will make the Nutrition Facts (NF) label for each of these food labels available to all participants. The study will focus on the following types of consumer reaction: (1) Identification of the healthier product in a pair of products; (2) judgments about a food product in terms of its nutritional qualities, overall healthfulness, health benefits, and other characteristics such as taste; (3) judgments about a nutrition information scheme in terms of its credibility and helpfulness in conveying the product's nutritional qualities and in assisting intake decisions; (4) impact of the labeling conditions (1) to (3) on the use of the Nutrition Facts label; and (5) time spent on product identification and judgment. To help understand consumer reaction, the study will also collect information on participants' background, including but not limited to consumption and perceptions of food products, nutrition attitudes and practice, food label use, and health status.

In addition, Study 1 will include a separate face-to-face eye-tracking research using a separate sample of 30 adult consumers to examine their label viewing patterns when they are asked to judge product attributes and to compare products. This research is included in Study 1 to explore the usefulness of the methodology of eye-tracking for future consumer research. Eye-tracking participants will be recruited by a contractor from members of a commercial database of consumers who express interest in participation and meet the selection criteria.

Study 1 will help the agency primarily in understanding how U.S. consumers would choose and perceive products in response to the five labeling conditions. The study will also enhance the agency's understanding of the relationships between consumer background and reaction to FOP information. This information will help the agency in its future deliberation of FOP related labeling actions, such as regulations and consumer education, to provide better information to consumers to assist their dietary choices. Because this is an experimental study, its results will not be used to develop population estimates.

In the **Federal Register** of June 1, 2009 (74 FR 26244), FDA published a 60-day notice requesting public comment on the Experimental Study of Nutrition Symbols on Food Packages (Study 1). The agency received seven responses, some of them containing multiple comments. Two comments raised issues that were outside the scope of the comment request on the information collection provisions and will not be discussed here. Among the relevant comments, all supported the proposed research. The following is a summary of the relevant comments and the agency's response to the comments:

(Comment 1) One comment questioned the inclusion in the study of questions about perceived taste and health benefits of products, dietary supplement use, and functional health literacy, stating that these questions do not seem to focus on the study objective of discerning consumer use and understanding of nutrition symbols on food packages. Another comment stated that ''diabetes or high blood sugar'' and ''obesity or overweight'' should be removed from perceived health benefits because FDA has not approved health claims for these conditions.

(Response 1) First, we disagree that questions about perceived health benefits and, perceived taste are outside the scope of the study. The purpose of the study is to understand consumer response to a sample of existing FOP nutrition labeling schemes. The study will help the agency evaluate the current situation and will provide information that will be important to any future deliberations of the agency's response to the various nutrition information schemes. Product perceptions (including nutrient levels, health benefits, and taste) are inferences consumers often make from labeling information. It is well known that some consumers perceive a tradeoff between nutrition and taste. Hence, it is within the scope of the study to collect such information to obtain a more complete understanding of consumer response to nutrition information schemes and to use it to tease out the effects of these schemes on product choices and perceptions. In addition, such information will enhance our understanding of consumer response to food labeling in general. We note that we have decided to remove the questions on use of dietary supplements and functional health literacy due to the length of the questionnaire.

Second, we disagree that ''diabetes or high blood sugar'' and ''obesity or overweight'' should be removed from the list of possible perceived health benefits because the agency has not approved health claims for these conditions. Diabetes and obesity are health conditions that have been linked to dietary quality, which is influenced by consumer choices and perceptions of food products. Furthermore, perception of the relationships between a food product and the risk of these two health conditions are part of inferences consumers often make from labeling information. Whether there exist health claims for these conditions is irrelevant.

(Comment 2) One comment noted that the questions seem to be testing specific symbols, rather than the concept of FOP nutrition information schemes. The comment also noted along the same lines that the it was not clear how FDA decided which symbols to test but noted that the symbols to be tested include symbols that are used in labeling (e.g., store shelf), rather than on the FOP. Another comment suggested that the Guiding Stars symbol would be an important element in the proposed study.

(Response 2) The comment is correct that the questions in this study are designed to test specific symbols used on packages, rather than the concept of FOP symbols. Smart Choices Program and Guideline Daily Amounts symbols have been selected because they are among the most widely used FOP symbols in the United States. The

Traffic Light type symbol has been selected because it is one of the FOP symbols used in the United Kingdom. The other two symbol schemes, NF only and no FOP scheme, have been selected to examine how product choice and perceptions would differ if consumers ignore the front package and turn to the NF label for product information or are not provided any nutrition information on the FOP. We have decided to focus at the present time exclusively on FOP symbols rather than on FOP and shelf tag symbols because consumers are more likely to see FOP symbols on nationally distributed products than shelf-tag symbols that can only be found in limited locations. Therefore, we have omitted the Guiding Stars and NuVal symbols from the study.

(Comment 3) One comment suggested that a question series could be developed to compare consumer response to three versions of labeling approaches: With no nutrition symbol, with a nutrition symbol, and with an FDA authorized health claim appropriate to the food.

(Response 3) We appreciate the suggestion to compare consumer responses to different versions of labeling approaches: With no nutrition symbol, with a nutrition symbol, and with claims that can be used under current regulatory framework, e.g., authorized health claims and nutrient content claims. Such research may be useful in the future. Nevertheless, due to the scarcity of information regarding consumer understanding and use of existing nutrition symbols in the domestic market, we consider it most useful at this time to conduct the planned research, which does include a comparison between no nutrition symbol and the presence of a nutrition symbol.

(Comment 4) A comment recommended that the study focus more broadly on consumer research issues that have not yet been fully answered by the limited research conducted to date. These issues include: Consumers' focus on nutrition symbols; the nutrition symbols that are most helpful to consumers; the nutritional elements that a symbol should reflect; the ideal placement of a symbol on the package; the effects of multiple symbols on consumer decision-making; the effects of the presence of a health claim on consumer use of nutrition symbols or the NF label; whether public or private sector oversight has any impact on the effect on consumers of a nutrition symbol program; use of symbols and behavioral changes; and consumer interpretation of symbols.

(Response 4) We agree that these issues are important for understanding the impacts of nutrition symbols on consumers. In fact, the proposed study has been designed to help provide information on several of the recommended issues, such as whether consumers focus in on nutrition symbols (using the eye-tracking study) and how consumers interpret symbols (using the experimental study). In addition, we note that we have added Study 2 to examine which of a wide range of symbol schemes may be most helpful to consumers. We agree, however, that further research will be needed.

(Comment 5) A comment questioned whether a comparison between a pair of products of the same product category and same type of symbol, but with different nutritional profiles, can be used to assess the various symbol systems and front-of-package v. shelf-tag systems. The comment stated that different systems present different information on the label or tag.

(Response 5) We appreciate the comment. One of the objectives of the study is to examine identification of the more nutritious product in a pair of products. It is precisely because different systems present different information on the front of package that we want to use this comparison to examine whether and how much respondents can discern two nutritionally different products when they see FOP symbols of different content/design. We hope to reject the hypothesis that there is no difference between different systems, e.g., product choices and perceptions are the same regardless of the type of symbol that shows on a product package. We also note that we have decided to omit shelf-tag symbols in this study.

(Comment 6) A comment questioned whether a comparison between a pair of products of different product categories but with the same type of symbol and different nutritional profiles, can be used to assess the symbol systems to be examined in this study. The comment stated that these symbol systems are designed to allow comparisons between products within a category rather than comparisons of products between categories.

(Response 6) We disagree that the comparison in question cannot be used to assess the target symbol systems. Though these systems are designed for within-category product comparisons, it is unknown whether consumers are aware of the intent. If consumers see the same type of symbol on various products, e.g., yogurt and cereal, some of them may infer these products possess the same or similar nutritional characteristics. In addition, the pair of products that will be compared have been selected because they are possible substitutes for each other for an eating occasion, e.g., yogurt and cereal. Unless these possibilities can be ruled out, it is within the scope of this study to include the comparison in question because it will provide information about consumer understanding of these symbols.

(Comment 7) One comment raised the issue of the representativeness of the study. It stated that the online sample should be balanced to reflect U.S. population demographics and controlled for grocery shopper status, category purchase and use status; that each test cell should be balanced accordingly; and that the study should be conducted in both English and Spanish so not to underrepresent non-English speaking demographics of the U.S. population.

(Response 7) We disagree that the study sample as well as each test cell should be balanced to reflect the U.S. population. The study is an experimental study aimed at establishing valid comparisons of respondents' reactions to different symbols and foods, rather than generating reliable population estimates. Furthermore, balancing a non-probability sample (such as the sample used in this study and most other online samples) or each test cell generated from the sample, does not necessarily make the study results representative. Because the study is not intended to generate population estimates, we also disagree that the study should control for grocery shopper status, category purchase, and use status. We recognize the usefulness in and importance of understanding non-English speaking consumers' response to food labeling and will consider addressing this need in future studies.

(Comment 8) A comment recommended that the study consider asking about perceived levels of nutrients-to-encourage separately from perceived levels of nutrients-to-limit, and about how symbols reinforce basic information such as food groups and servings.

(Response 8) We agree that it is useful to examine consumer perceptions of nutrients-to-encourage in addition to nutrients-to-limit, and have included four nutrients-to encourage (calcium, fiber, Vitamin A, and Vitamin C) in the revised questionnaire. We also agree that it would be useful to examine in future research how symbols reinforce basic information such as food groups and servings.

(Comment 9) A comment stated that FDA should apply science and transparency in its research intentions and study design.

(Response 9) We appreciate the comment that FDA should apply science and transparency in its research intentions and study design. We hope Responses 1 to 6 in this document will help clarify some of the critical elements in the agency's rationale behind the purpose of the study and the study design.

(Comment 10) A comment suggested that the word ''nutritious'' rather than ''healthy'' should be used because the latter could be associated by respondents with considerations other than nutrition and has a regulatory meaning.

(Response 10) We disagree that the word ''healthy'' should not be used because it has a regulatory meaning. We are not aware of any research that suggests consumers are aware that the word ''healthy'' has a specific regulatory definition when used in food labeling. We agree that ''healthy'' may be less precise than ''nutritious'' for what the study intends to measure. Existing consumer research, however, indicates that consumers associate ''healthy'' more with nutritional qualities of a food product than with other considerations such as freshness. Therefore, we will retain the word ''healthy'' in this study.

(Comment 11) A comment stated that the study plan of ''showing front panels which are full-color, three-dimensional, and patterned after existing labels in the market'' would not remove the effects of brands on responses but would confound the analysis.

(Response 11) We disagree with this comment. We have taken a great deal of care in developing the mock front panels by (1) Omitting any pictures or words that may provide clues to the brand name of a product; (2) mixing graphic components from different existing labels or creating original graphics in an attempt to disassociate the mock label with any existing brands; and (3) using fictitious names and addresses of the manufacturer. We believe these actions will minimize potential confounding effects, if any, caused by brands.

(Comment 12) A comment suggested that the test symbols should be accurately represented and have NF declarations that support the symbol-product combinations; if a symbol is used on a product for study purposes, but not necessarily in the market, the comment states that the difference should be explained in the analysis.

(Response 12) We understand the concern. In designing the symbols for this study, the agency has used available information from symbol schemes' Web sites, created certain label information, and omitted symbols in some experimental conditions for the purpose the study. The agency will inform respondents that the labels they see in this study may or may not be the same as the ones they see in the marketplace and mention this in the analysis.

(Comment 13) A comment stated that some questions could be answered not because of one's understanding of the nutrition symbol but because of the respondent's previous knowledge or perception of the product or product category, and that some of the prior knowledge questions may prime symbol responses and should be moved to later in the questionnaire to minimize potential bias.

(Response 13) We agree that there is a possibility that some respondents may be able to answer some questions by drawing on their own previous knowledge or perception of the product or product category, rather than on their perception and understanding of the nutrition symbol on a test product. The study asks questions about respondents' previous knowledge or perception of the product or product category precisely because we want to minimize the risk for confounding as a result of previous knowledge.

We disagree that some of the prior knowledge questions should be moved to later in the questionnaire. Moving prior knowledge questions to follow symbol response questions can cause respondents to choose knowledge responses considered consistent with their symbol responses, thus increasing potential measurement errors in knowledge response. To minimize potential biases caused by asking prior knowledge before symbols response, we will have the two phases of the study (Phase 1 on prior knowledge and Phase 2 on label response and other topics) administered separately and a week apart from each other to the same respondents. The agency has implemented this strategy in one of its previous experimental studies.

(Comment 14) A comment questioned whether forced exposure to test symbols would make the study results not representative of in-market realities.

(Response 14) We recognize that forced exposure sometimes can restrict the applicability of the results to actual consumer responses in the store. Nonetheless, the objective of the study is to understand consumer reactions to one specific piece of labeling information, the nutrition symbol, rather than to all or other pieces of labeling information. We think that using forced exposure in a controlled environment increases the likelihood that observed outcomes are caused by symbols rather than prior knowledge and individual characteristics. Otherwise, it would be difficult to ascertain whether respondents have noticed the test symbols, which in turn would raise questions about the validity of the results. On the other hand, if the objective of the study was to gather market-representative results, then alternative methodologies such as modeling sales data may be more appropriate.

(Comment 15) A comment stated that the proposed product categories (cereal, savory snack, and frozen meal) would not be appropriate for product comparison tasks because they are not substitutes for each other in the diet.

(Response 15) We disagree that these product categories are not appropriate. We will use two similar products in a given category, e.g., chips and crackers in the savory snack category, for within-category product comparison; we will use two substitute products, e.g., cereal and yogurt, for between-category product comparison.

(Comment 16) A comment recommended that product consumption and purchase questions be moved from the beginning to a later section of the questionnaire and that these questions focus on at-home practices only.

(Response 16) We disagree that these questions need to be moved from the beginning of the questionnaire. They are relatively easy to answer and can serve as a warm-up to focus respondents' attention on the food products in question. We have revised the questionnaire to help respondents understand that the questions ask about grocery shopping rather than food purchases at away-from-home eating establishments.

(Comment 17) A comment stated that it would be important to record label reading practices for the food categories included in the study.

(Response 17) We agree that it would be important to record label reading practices for the food categories included in the study. We have added two questions to collect this information.

(Comment 18) A comment offered suggestions on simplifying questions, improving response types, scales and response formats, and ways to distinguish responses to the front and back of a label.

(Response 18) We appreciate the comment and suggestions. We have incorporated many of the helpful suggestions in the revised questionnaire

and will make other necessary and appropriate revisions to the questionnaire based on cognitive interviews and pretests.

(Comment 19) A comment stated that the proposed study is more likely to require close to 30 minutes, rather than the proposed 15 minutes, to complete. Another comment stated that the commenter's experience with a 20-minute online survey similar to the proposed study suggested there was no negative feedback on the burden of data collection.

(Response 19) We agree that the original estimate (15 minutes) was relatively low and has adjusted the content of the study so it will be completed in 20 minutes.

(Comment 20) One comment asked the agency to publish the revised questionnaire for public comment prior to initiating the study.

(Response 20) We appreciate the suggestion for the agency to publish the revised questionnaire for public comment prior to initiating the study. Per the PRA, a copy of the revised questionnaire is attached to the supporting statement for public comment.

(Comment 21) A comment suggested that the agency should increase the sample size of the eye tracking study from 30 individuals to 100 to 200 individuals to provide results that are more reliable.

(Response 21) We appreciate the suggestion to increase the sample size of the eye tracking study from 30 individuals to 100 to 200 individuals to provide results that are more reliable. As stated previously, the purpose of the eye-tracking component in this study is exploratory. We do not intend to use the information from this study to generate any reliable estimates of consumer labeling viewing behaviors. We will consider a larger eye-tracking study when resources become available and we have the need to collect reliable estimates of the behaviors.

(Comment 22) Another comment recommended that the study consider using conjoint analysis to determine how consumers value different features of a given symbol.

(Response 22) We appreciate the suggestion to use conjoint analysis for this study. The purpose of the proposed study is to investigate how consumers understand various FOP labeling schemes. In contrast, conjoint analyses are employed in most studies to examine consumer preferences toward different objects, which may include FOP labeling schemes. Therefore, despite the wide use of conjoint analysis in academic and industry research, the agency will need to establish the appropriateness and feasibility of conjoint analysis for research with similar objectives as the proposed study before it adopts the methodology.

B. Study 2

Study 2 will examine nine FOP nutrition labeling schemes in addition to two controls: (1) The presence of a ''Nutrition Tips'' scheme on the FOP that shows: (a) Per-serving amounts of calories, total fat, saturated fat, sugar, sodium; and (b) interpretive words and colors of the amounts (high-red, medium-yellow, and low-green), with each word wrapped in a colored rectangle; (2) same as (1) but in black and white; (3) the presence of a ''Nutrition Tips'' scheme on the FOP that shows: (a) Per-serving amount of calories and % Daily Values (DV) of calories, total fat, saturated fat, sugar, sodium; (b) interpretive words of the % DV (high, medium, and low); and (c) is in black and white; (4) the presence of a ''Nutrition Tips'' scheme on the FOP, patterned after one variant of the U.K. Multiple Traffic Light scheme, that shows: (a) per-serving amounts of calories, total fat, saturated fat, sugar, sodium; (b) interpretive words and colors of the amounts (high-red, medium-yellow, and low-green) with each word wrapped in a colored circle; and (c) the measure of a serving (e.g., 1 cup); (5) same as (4) except that a different set of colors is used (high-pastel red, medium-pastel green, and low-pastel blue); (6) the presence of a ''Calorie Count'' scheme on the FOP that shows the amount of calories per serving and total amount of calories in the package; (7) the presence of a ''Calorie Count'' scheme on the FOP that shows the amount of calories per serving and the number of servings per package; (8) the presence of a ''Nutrition Rating'' scheme on the FOP that shows: (a) The numerical value and number of stars (out of five stars) representing the overall nutritional quality of the product; and (b) the amount of calories per serving; (9) the presence of a green ''Healthy Check'' scheme on the FOP that includes the word ''healthy'' and a separate box showing the amount of calories per serving and the number of servings per package; (10) a control that shows only the Nutrition Facts label; and (11) a control that shows no FOP nutrition information.

Study 2 will randomly assign each of its 4,800 participants to the 88 experimental conditions (11 labeling conditions x 4 product categories x 2 levels of choice difficulty). The study will focus on the following types of consumer reaction: (1) Accuracy and speed in a two product choice task that requires selection of the healthier product; (2) relevancy given for choice based on thematic coding of open-ended responses; (3) perceptions of long term consequences of regularly including the chosen product in one's diet; (4) perceptions of selected nutrient levels in the chosen product; (5) likelihood of truncated information search when answering product perception questions; and (6) perceptions of credibility and helpfulness of the labeling scheme. To help understand consumer reaction, the study will also collect information on participants' nutrition consciousness.

The purpose of Study 2 is to help the agency compare the relative effectiveness of a wide range of nutrition labeling schemes along with certain specific design features (e.g., color, presentation of calorie and serving size information) in helping consumers make healthier food choices. The results of the study will not be used to develop population estimates.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
(Study 1 and Study 2) Cognitive interview screener	288	1	288	0.083	24	0	0
(Study 1 and Study 2) Cognitive interview	36	1	36	1	36	0	0
(Study 1 and Study 2) Pretest invitation	3,200	1	3,200	0.033	106	0	0
(Study 1) Pretest	200	1	200	0.33	66	0	0
(Study 2) Pretest	200	1	200	0.25	50	0	0
(Study 1 and Study 2) Survey invitation	38,400	1	38,400	0.033	1,267	0	0
(Study 1) Survey	2,400	1	2,400	.33	792	0	0
(Study 2) Survey	4,800	1	4,800	0.25	1,200	0	0
(Study 1) Eye-tracking screener	240	1	240	0.083	20	0	0
(Study 1) Eye-tracking	30	1	30	1	30	0	0
Total					3,591	0	0

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

In the 60-day notice that published on June 1, 2009, we estimated a total burden of 1,417 hours for Study 1. In this document, table 1 has been modified to add the estimated burden hours associated with new Study 2 and to reflect our re-evaluation of the time it takes to complete the questionnaire in Study 1. The new total estimated burden is 3,591 hours.

To help design and refine the questionnaires to be used for the experimental studies, we will conduct cognitive interviews by screening 288 adult consumers in order to obtain 36 participants in the interviews. Each screening is expected to take 5 minutes (0.083 hours) and each cognitive interview is expected to take 1 hour. The total for cognitive interview activities is 60 hours (24 hours + 36 hours). Subsequently, we will conduct pretests of the survey questionnaires before they are administered. We expect that 3,200 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of two online consumer panels to have 400 of them complete a 20-minute (0.33 hours) and a 15-minute (0.25 hours) pretest, respectively. The total for the pretest activities is 223 hours (106 hours + 66 hours + 50 hours). For the survey, we estimate that 38,400 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of two online consumer panels to have 2,400 of them complete a 20-minute (0.33 hours) questionnaire for Study 1 and 4,800 of them complete a 15-minute (0.25 hours) questionnaire for Study 2, respectively. The total for the survey activities is 3,259 hours (1,267 hours + 792 hours + 1,200 hours). To conduct the eye-tracking study, we expect to screen 240 adult consumers, each taking 5 minutes (0.083 hours), to have 30 of them participate in a 1-hour interview. The total for the eye-tracking activities is 50 hours (20 hours + 30 hours). Thus, the total estimated burden is 3,591 hours. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

II. References

The following references have been placed on display in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified all Web site addresses, but FDA is not responsible for any subsequent changes

to the Web sites after this document publishes in the **Federal Register**.)

1. Malam, S., S. Clegg, S. Kirwan, and S. McGinigal, ''Comprehension and Use of UK Nutrition Signpost Labelling Schemes,'' report prepared for Food Standards Agency, May 2009.

2. Borgmeier, I, and J. Westenhoefer, ''Impact of Different Food Label Formats on Healthiness Evaluation and Food Choice of Consumers: a Randomized-Controlled Study,'' *BMC Public Health*, 9: 184, 2009, accessed online at *http://www.biomedcentral.com/content/pdf/1471-2458-9-184.pdf*.

3. Kelly, B, C. Hughes, K. Chapman, J.C.-Y. Louie, H. Dixon, J. Crawford, L. King, M. Daube, T. Slevin, ''Consumer Testing of the Acceptability and Effectiveness of Front-of-Pack Food Labelling Systems for the Australian Grocery Market,'' Health Promotion International 24(2):120–9, 2009.

4. Feunekes, G.I.J., I.A. Gortemaker, A.A. Willems, R. Lion, and M. van den Kommer, ''Front-of-pack Nutrition Labelling: Testing Effectiveness of Different Nutrition Labelling Formats Front-of-pack in Four European Countries,'' *Appetite*, 50:57–70, 2008.

Dated: November 24, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–28699 Filed 11–30–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: National Health Service Corps Travel Request Worksheet (OMB No. 0915–0278)—Extension

Clinicians participating in the HRSA National Health Service Corps (NHSC) Scholarship Program use the online Travel Request Worksheet to receive travel funds from the Federal Government to perform pre-employment interviews at sites on the NHSC's Opportunities List.

The travel approval process is initiated when a scholar notifies the NHSC of an impending interview at one or more NHSC approved practice sites. The Travel Request Worksheet is also used to initiate the relocation process after a NHSC scholar has successfully been matched to an approved practice site. Upon receipt of the Travel Request Worksheet, the NHSC will review and approve or disapprove the request and promptly notify the scholar and the NHSC logistics contractor regarding travel arrangements and authorization of the funding for the site visit or relocation.

The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Travel Request Worksheet	140	2	280	.06	16.8

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: November 24, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Health Education Assistance Loan (HEAL) Program: Forms (OMB No. 0915–0043 Extension)

The Health Education Assistance Loan (HEAL) program continues to administer and monitor outstanding loans which were provided to eligible students to pay for educational costs in a number of health professions. HEAL forms collect information that is required for responsible program management. The HEAL Repayment Schedule, Fixed and Variable, provides the borrower with the cost of a HEAL loan, the number and amount of payments, and the Truth-in-Lending disclosures. The Lender's Report on HEAL Student Loans Outstanding (Call Report), provides information on the status of loans outstanding by the number of borrowers and total number of loans whose loan payments are in various stages of the loan cycle, such as student education and repayment, and the corresponding dollar amounts. These forms are needed to provide borrowers with information on the cost of their loan(s) and to determine which