ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	No. of respondents	No. of responses per respondent	Avg. burden per response (in hrs)	Total burden (in hrs)
AI/AN Tribal Grantees ...	Traditional Foods Shared Data Elements	17	2	2	68
	One-Time Retrospective Data Collection	6	1	2	12
Total	.....	.....	.....	.....	80

Dated: November 10, 2010.

Carol E. Walker,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–28930 Filed 11–16–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0532]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Nutrition Facts Label Formats

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 (the PRA).

DATES: Fax written comments on the collection of information by December 17, 2010.

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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910—New and title "Experimental Study of Nutrition Facts Label Formats." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., 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.

I. Experimental Study of Nutrition Facts Label Format—(OMB Control No. 0910—New)

Nutrition information is required on most packaged foods and this information must be provided in a specific format as defined in 21 CFR 101.9. When FDA was determining which Nutrition Facts label format to require, the Agency undertook consumer research to evaluate alternatives (Refs. 1, 2, and 3). More recently, FDA conducted qualitative consumer research on the format of the Nutrition Facts label on behalf of the Agency's Obesity Working Group (OWG) (Ref. 4), which was formed in 2003 and tasked with outlining a plan to help confront the problem of obesity in the United States (Ref. 5). In addition to conducting consumer research, in response to the OWG plan FDA issued two advance notices of proposed rulemaking (ANPRM) requesting comments on format changes to the Nutrition Facts label. One ANPRM requested comments on whether and, if so, how to give greater emphasis to calories on the Nutrition Facts label (Ref. 6) and the other requested comments on whether and, if so, how to amend the Agency's serving size regulations (Ref. 7). In 2007, FDA issued an ANPRM requesting comments on whether the Agency should require that certain nutrients be added or removed from the Nutrition Facts label (Ref. 8).

FDA conducts consumer research under its broad statutory authority, set forth in section 903(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(2)(A), 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 FD&C Act.

FDA is proposing to conduct an experimental study to quantitatively assess consumer reactions to potential options for modifying the Nutrition Facts label format. The purpose of the study is to help enhance FDA's understanding of consumer comprehension and acceptance of modifications to the Nutrition Facts label format. The study is part of the Agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets.

The proposed study will use a Web-based experiment to collect information from a sample of adult members in an online consumer panel established by a contractor. The study plans to randomly assign each of 10,000 participants to view Nutrition Facts labels from a set of Nutrition Facts labels that vary by the format, the type of food product, and the quality of nutritional attributes of the product. The study will focus on the following types of consumer reactions: (1) Judgments about a food product in terms of its nutritional attributes and overall healthfulness and (2) ability to use the Nutrition Facts label to, for example, calculate calories and estimate serving sizes needed to meet objectives. To help understand consumer reactions, the study will also collect information on participants' background, including but not limited to use of the Nutrition Facts label and health status.

The study results will be used to help the Agency to understand whether modifications to the Nutrition Facts label format could help consumers make informed food choices. The results of the experimental study will not be used to develop population estimates.

In the **Federal Register** of November 18, 2009 (74 FR 59553), FDA published a 60-day notice requesting public comment on the proposed collection of information. The Agency received 36 responses, some of them containing multiple comments. 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 topics of the collection of information. These non-responsive comments are not addressed.

(Comment 1) Several comments cited the importance of studying ways to improve the Nutrition Facts label on

packaged foods and commended FDA for doing it.

(Response 1) FDA agrees that the study will help FDA learn how consumers react and respond to Nutrition Facts label modification options presented.

(Comment 2) One comment suggested adding questions about product purchase intent, amount the consumer would likely eat, and impression of the product's taste and safety.

(Response 2) FDA agrees that these questions are worthwhile and has included questions on product purchase intent. However, given the study designs focus solely on the nutrition label for use to choose healthier and lower calorie products and mode of data collection (Internet), questions on amount of product likely to be eaten and on taste are not meaningful to include.

(Comment 3) One comment suggested that the study include various formats with different methods of presenting nutrition information be tested so that the format can be found which helps consumers understand the total nutrition package without causing confusion regarding the other properties of the product.

(Response 3) FDA agrees that various formats should be tested that help consumers make more informed decisions about the healthfulness of the product. We will include questions about the product to test how consumers use the Nutrition Facts label for making those evaluations.

(Comment 4) One comment suggested the inclusion of real-time, one-on-one chats between live moderators and respondents during the fielding of the study to enhance the quality of the quantitative data collected.

(Response 4) FDA disagrees with this suggestion. FDA has already conducted a series of eight focus groups to learn how and why consumers react to the formats being tested. Also, prior to conducting the on-line experiment, FDA will conduct at least nine one-on-one interviews where we observe respondents taking the questionnaire, and get their feedback about what they were thinking as they answered each question. We believe that, taken together, the focus groups and the one-on-one interviews will give us a good feel as to why respondents answer the questions as they do.

(Comment 5) A number of comments asked the Agency to publish the revised instrument and mock stimuli for public comment prior to initiating the study. They had questions and recommendations about the design of the experiment, for example, whether there will be a control group and how many designs will be shown to the consumers and how many label formats will be tested and whether the subjects will be asked to rank the different formats in terms of preference.

(Response 5) We appreciate the suggestion for the Agency to publish the instrument and stimuli for public comment prior to initiating the study. Per the PRA, a copy of the revised instrument is attached to the supporting statement for public comment. We will also include examples of stimuli as an appendix of the supporting document. FDA will have a control group for this experiment. Ten different label formats will be tested. Each subject will only perform two tasks—an evaluation of a single label and a label comparison task.

(Comment 6) Several comments were about who should be included in the study. One comment said that FDA should give careful consideration to the gender and age distribution of the study subjects and that older subjects may have difficulty in using the Web. One comment said it was important to include people with special health concerns, those that do the majority of grocery shopping or food preparation for their households, and groups that may be underrepresented online.

(Response 6) FDA agrees that demographic factors such as age and gender, health concerns, grocery shopping, and food preparation experiences are important factors. FDA will collect the previously mentioned information and include them in the analyses. FDA will aim to have a sample resemble the American adult population. FDA will do pre-tests to make sure everyone can read and understand the survey.

(Comment 7) One comment suggested that FDA should consider as part of the proposed study how consumers interpret the Nutrition Facts label in the context of all the other information on the package, and raised the question of whether the information on the Nutrition Facts label would be lost, diluted, or confounded by all of the other information that appears on the package. The comment suggested that, as part of the study design, FDA could present the Nutrition Facts label by itself and also how it would appear alongside the other package information, to see if consumers view or interpret the Nutrition Facts label differently in light of the total package.

(Response 7) While FDA agrees that the Nutrition Facts label is perceived in the context of the entire package, the goal of this study is to test various modifications to the Nutrition Facts label that would be suitable for all food products regardless of the context of the package. The study design proposes to test different options of modified Nutrition Facts label without other aspects of the food package.

(Comment 8) One comment stated that, in selecting the final sample for the experimental study, FDA should consider whether a certain percentage of the subjects should be recruited based on their concerns about allergy information. The comment stated that although most of the information on the Nutrition Facts label has relevance to all consumers, label information about allergens may be of interest only to a relatively small number of subjects who have food allergies. The comment suggested that the responses from this group could be analyzed separately, in addition as part of the total sample.

(Response 8) It is estimated that the prevalence of food allergies ranges from approximately 1 to 10 percent of the population (Ref. 9). The study will use a convenience sample (not a representative sample) consisting of members of an online panel, 18 years of age or older. Therefore, the number of respondents who have food allergies or are caretakers of children who have food allergies would be too small for the purpose of statistically sound analysis.

(Comment 9) One comment asked that FDA consider ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology.

(Response 9) FDA has taken steps to minimize the burden of data collection on respondents. Participants of the study will be members of the existing online panel and data will be collected through the Internet. Respondents will be sent e-mail invitations to participate in the study.

(Comment 10) One comment asked whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.

(Response 10) FDA believes that collecting this information is necessary for FDA's regulatory oversight of the Nutrition Facts label. Because one of the purposes for initially developing and implementing the Nutrition Facts label was to help consumers make informed food choices, it is important for FDA to be able to evaluate whether consumers understand how to properly interpret the label, especially for health purposes.

(Comment 11) One comment requested that FDA consider using some or all of the label format changes suggested by the Center for Science in the Public Interest (CSPI) (Ref. 10).

(Response 11) CSPI suggested extensive changes to the Nutrition Facts label that affect many parts of the label. In this research, the Agency is focused on how consumers use labels for products that are customarily consumed at one eating occasion but may contain more than one serving per container as well as on how consumers react to different ways that calorie information is declared on the label. FDA believes these changes have the potential to be among the most useful changes to help consumers make informed choices. Therefore, FDA identified and chose the proposed formats, such as dual column formats and prominence of calorie formats, for this study. The variety of different experimental conditions for just these changes requires a very large number of respondents. It is not feasible to test the additional extensive changes such as those suggested by CSPI in this study because the number of respondents needed would become unmanageable.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Cognitive interview screener	96	1	96	0.083	8
Cognitive interview	12	1	12	1	12
Pretest invitation	1,000	1	1,000	0.033	33
Pretest	150	1	150	0.25	38
Experiment invitation	50,000	1	50,000	0.033	1,650
Experiment	10,000	1	10,000	0.25	2,500
Total					4,241

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

In the 60-day notice that published in the **Federal Register** of November 18, 2009, we estimated a total burden of 1,595 hours for the study. In this document, table 1 has been modified to reflect our re-evaluation of the original study design. The new total estimated burden is 4,241 hours.

To help design and refine the questionnaire to be used for the experimental study, we plan to conduct cognitive interviews by screening 96 adult consumers in order to obtain 12 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 20 hours (8 hours + 12 hours). Subsequently, we plan to conduct pretests of the questionnaire before it is administered in the study. We expect that 1,000 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of an online consumer panel to have 150 of them complete a 15-minute (0.25 hours) pretest. The total for the pretest activities is 71 hours (33 hours + 38 hours). For the experiment, we estimate that 50,000 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of an online consumer panel to have 10,000 of them complete a 15-minute (0.25 hours) questionnaire. The total for the experiment activities is 4,150 hours (1,650 hours + 2,500 hours). Thus, the total estimated burden is 4,241 hours. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

II. References

1. Levy A., S. Fein, and R. Schucker, "Nutrition Labeling Formats: Performance and Preference," *Food Technology* 45: 116–121, 1991.
2. Levy A., S. Fein, and R. Schucker, "More Effective Nutrition Label Formats Are Not Necessarily Preferred," *Journal of the American Dietetic Association* 92: 1230–1234, 1992.
3. Levy A., S. Fein, and R. Schucker, "Performance Characteristics of Seven Nutrition Label Formats," *Journal of Public Policy and Marketing* 15: 1–15, 1996.
4. Lando A. and J. Labiner-Wolfe, "Helping Consumers to Make More Healthful Food Choices: Consumer Views on Modifying Food Labels and Providing Point-of-Purchase Nutrition Information at Quick-Service Restaurants," *Journal of Nutrition Education and Behavior* 39: 157–163, 2007.
5. U.S. Food and Drug Administration, Calories Count: Report of the Working Group on Obesity, 2004, (*http://www.fda.gov/Food/LabelingNutrition/ReportsResearch/ucm081696.htm*).
6. 70 FR 17008, April 4 2005.
7. 70 FR 17010, April 4 2005.
8. 72 FR 62149, November 2 2007.
9. Schnieder Chafer, J.J., S.J. Newbery, M.A. Riedl, *et al.,* "Diagnosing and Managing Common Food Allergies: A Systematic Review," *Journal of the American Medical Association* 303(18): 1848–1856.
10. Silverglade, B and I.R. Heller, "Food Labeling Chaos: The Case for Reform," Center for Science in the Public Interest, March 2010, available at: *http://www.cspinet.org/new/pdf/food_labeling_chaos_report.pdf.*

Dated: November 10, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–28966 Filed 11–16–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; NIH NCI Central Institutional Review Board (CIRB) Initiative (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 16, 2010 (75 FR 49938) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it