ANNUALIZED SUMMARY TABLE

Respondents	Number of respondents	Total responses	Total annualized hour burden *
Adolescent	200	2,000	1,450
Collateral	200	5,000	910
Project Coordinator	4	1,204	261
Telephone Support Volunteer	8	7,608	2,766
Social Network Site Moderator	1	53	26.25
Family Program Clinician	4	5,604	1,115
Support Services Supervisor	1	37	30.25
Total	418	21,506	6,558.50

Written comments and recommendations concerning the proposed information collection should be sent by December 18, 2009 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–5806.

Dated: November 12, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–27641 Filed 11–17–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0532]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on an experimental study of Nutrition Facts label formats.

DATES: Submit written or electronic comments on the collection of information by January 19, 2010.

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

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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

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

Experimental Study of Nutrition Facts Label Formats—(Section 903(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(C))) (OMB Control Number 0910–NEW)

I. Description

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).

* Total Annualized Hour Burden = Total Responses × Hours per Response.

FDA conducts consumer research under its broad statutory authority, set forth in section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (the act), to protect the public health by ensuring that foods are ''safe, wholesome, sanitary, and properly labeled,'' and in section 903(d)(2)(C) of the act, to conduct research relating to foods, drugs, cosmetics, and devices in carrying out the 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 3,600 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 to make informed food choices. The results of the experimental 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]

Portion of Study	No. 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	0.20	30
Experiment invitation	24,000	1	24,000	0.033	792
Experiment	3,600	1	3,600	0.20	720
Total					1,595

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

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 12-minute (0.20 hours) pretest. The total for the pretest activities is 63 hours (33 hours + 30 hours). For the experiment, we estimate that 24,000 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of an online consumer panel to have 3,600 of them complete a 12-minute (0.20 hours) questionnaire. The total for the experiment activities is 1,512 hours (792 hours + 720 hours). Thus, the total estimated burden is 1,595 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 (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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.

Dated: November 12, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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