and help consumers adopt healthy lifestyles. The information will also help FDA and other Federal Agencies evaluate and track consumer awareness and behavior as outcome measures of their achievement in improving public health.

Description of Respondents: The respondents are adults, age 18 and older, drawn from the 50 States and the District of Columbia. Participation will be voluntary.

FDA bases its estimate of the number of respondents and the hours per response on its experience with previous Health and Diet Surveys. Prior to the administration of the Health and Diet Survey—General Topics, the Agency plans to conduct a pretest to identify and resolve potential problems. The pretest will be conducted with 27 participants; we estimate that it will take a respondent 15 minutes (0.25 hours) to complete the pretest, for a total of 6.75 hours, rounded to 7. The Agency will use a screener to select an eligible adult respondent in each household to participate in the survey. For the Health and Diet Survey—General Topics data collection activity, a total of 10,000 individuals in the 50 States and the District of Columbia will be screened by telephone. We estimate that it will take a respondent 1 minute (0.02 hours) to complete the screening, for a total of 200 hours. We estimate that 3,000 eligible adults will participate in the survey, each taking 15 minutes (0.25 hours), for a total of 750 hours. For the Health and Diet Survey—*Dietary Guidelines* Supplement data collection activity, 4,000 individuals in the 50 States and the District of Columbia will be screened by telephone. We estimate that it will take a respondent 1 minute (0.02 hours) to complete the screening questions, for a total of 80 hours. Of these respondents, 1,200 will complete the survey. We estimate that it will take a respondent 13 minutes (0.22 hours) to complete the entire survey, for a total of 264 hours. Thus, the total estimated burden is 1,301 hours.

In the **Federal Register** of January 7, 2011 (76 FR 1168), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments in response to the 30-day notice. The letters contained comments outside the scope of the four collection of information topics on which the notice solicits comments and, thus, will not be addressed here.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
General Topics: Pretest	27	1	27	15/60	7
General Topics: Screener	10,000	1	10,000	1/60	200
General Topics: Survey	3,000	1	3,000	15/60	750
Dietary Guidelines Supplement: Screener	4,000	1	4,000	1/60	80
Dietary Guidelines Supplement: Survey	1,200	1	1,200	13/60	264
Total					1,301

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the form "[number of minutes per response]/60".

Dated: May 12, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–12554 Filed 5–20–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0345]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study on Consumer Responses to Nutrition Facts Labels With Various Footnote Formats and Disclosure of Amounts of Vitamins and Minerals

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 a study entitled "Experimental Study on Consumer Responses to Nutrition Facts Labels With Various Footnote Formats and Disclosure of Amounts of Vitamins and Minerals."

DATES: Submit either electronic or written comments on the collection of information by July 22, 2011.

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, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 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.

I. Experimental Study on Consumer Responses to Nutrition Facts Labels With Various Footnote Formats and Disclosure of Amounts of Vitamins and Minerals—(OMB Control Number 0910-New)

Under the Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535), the Nutrition Facts label is required on most packaged foods, and this information must be provided in a specific format in accordance with the provisions of § 101.9 (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 through 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 (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 the **Federal Register** of November 2, 2007 (72 FR 62149) FDA issued an advance notice of proposed rulemaking (ANPRM) entitled, "Food Labeling: Revision of Reference Values and Mandatory Nutrients" (the 2007 ANPRM), which requested comments on a variety of topics related to a future proposed rule to update the presentation of nutrients and content of nutrient values on food labels. In the 2007 ANPRM, the Agency included a request for comments on how consumers use the percent Daily Value in the Nutrition Facts label when evaluating the nutritional content of food items and making purchases.

Research has suggested that consumers use the Nutrition Facts label in various ways, including, but not limited to, using the Nutrition Facts label to determine if products are high or low in a specific nutrient and to compare products (Ref. 6). One component of the Nutrition Facts label that serves as an aid in these uses is the percent Daily Value. Early consumer research indicated that the percent Daily Value format improved consumers' abilities to make correct dietary judgments about a food in the context of a total daily diet (Ref. 3), which led FDA to require both quantitative and percentage declarations of nutrient daily values in the Nutrition Facts label in the 1993 Nutrition Labeling final rule (58 FR 2079, January 6, 1993).

Research in subsequent years, however, suggested that consumers' understanding and use of percent Daily Value may be somewhat inconsistent (Refs. 7 and 8). Additionally, FDA has received several public comments suggesting that further research on percent Daily Values may be warranted, along with research on other modifications to the Nutrition Facts label. Suggested research on potential modifications includes research on: (1) The removal of the statements, "Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs"; (2) the removal of the table in the footnote that lists the Daily Values for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 and 2,500 calorie diets as described in § 101.9(d)(9); and (3) changes to the presentation of and amount of information provided in the Nutrition Facts label. Therefore, FDA, as part of its effort to promote public health, proposes to use this study to explore consumer responses to various food label formats for the footnote area of the Nutrition Facts label, including those that exhibit information such as various definitions for percent Daily Value and general guidelines for high and low nutrient levels. In addition, the Agency will use this study to explore consumer responses to inclusion of weight amount information in the declaration of vitamins and minerals described in § 101.9(c)(8)(ii) (i.e., vitamin A, vitamin C, calcium, and iron), which may have potential health value to consumers (Ref. 9).

The proposed collection of information is a controlled, randomized, experimental study. The study will use a Web-based survey, which will take about 15 minutes to complete, to collect information from 10,000 English-speaking adult members of an online consumer panel maintained by a contractor. The study will aim to recruit a sample that reflects the U.S. Census on gender, education, age, and ethnicity/race.

The study will randomly assign each of its participants to view a total of three label images from a set of food labels that will be created for the study and systematically varied in the presence or absence of the following items: (1) A definition for percent Daily Value, (2) a general guideline for "high" and "low" nutrient levels, and (3) weight amounts for vitamins and minerals. Various definitions for percent Daily Value may include, for example, "The percent Daily Value is the amount of a nutrient listed above that one serving of this product contributes to the daily diet"; "The percent Daily Value is the amount of a nutrient listed above that one serving of this product contributes to what you eat in a day"; and "The percent Daily Value is the amount of a nutrient listed above that one serving of this product contributes to a 2,000 calorie diet." A sample guideline for high and low nutrient levels may include, for example, "A percent Daily Value that is 5 percent or less is low, and 20 percent or more is high." To correspond with FDA's other experimental study of Nutrition Facts label formats described in the November 17, 2010, **Federal Register** (75 FR 70266), this study will evaluate performance of the footnote statements in combination with single and dual column labeling. Finally, the study will also examine effects of including reference to FDA within the Nutrition Facts footnote. All label images will be mock-ups resembling food labels that may be found in the marketplace. Images will show product identity (e.g., potato chips), but not any real or fictitious brand name.

The survey will ask its participants to view label images and answer questions about their understanding, perceptions, and reactions related to the viewed label. 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 healthiness; (2) ability to use the Nutrition Facts label to, for example, compare products and calculate the number of servings of a product needed to meet nutritional objectives; and (3) label perceptions (*e.g.,* helpfulness and credibility). 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 is part of the Agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets. Results of the study will be used primarily to enhance the Agency's understanding of how various potential modifications to the Nutrition Facts label may affect how consumers perceive a product or a label,

which may in turn affect their dietary choices. Results of the study will not be used to develop population estimates.

To help design and refine the questionnaire, FDA plans to conduct cognitive interviews by screening 72 panelists in order to obtain 9 participants in the interviews. Each screening is expected to take 5 minutes (0.083 hour) and each cognitive interview is expected to take 1 hour. The total for cognitive interview activities is 15 hours (6 hours + 9 hours). Subsequently, we plan to conduct pretests of the questionnaire before it is administered in the study. We expect that 1,600 invitations, each taking 2 minutes (0.033 hour), will need to be sent to panelists to have 200 of them complete a 15-minute (0.25 hour) pretest. The total for the pretest activities is 103 hours (53 hours + 50 hours). For the survey, we estimate that 80,000 invitations, each taking 2 minutes (0.033 hour) to complete, will need to be sent to the consumer panel to have 10,000 of its members complete a 15-minute (0.25 hour) questionnaire. The total for the survey activities is 5,140 hours (2,640 hours + 2,500 hours). Thus, the total estimated burden is 5,258 hours. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
Cognitive interview screener	72	1	72	5/60	6
Cognitive interview	9	1	9	1	9
Pretest invitation	1,600	1	1,600	2/60	53
Pretest	200	1	200	15/60	50
Survey invitation	80,000	1	80,000	2/60	2,640
Survey	10,000	1	10,000	15/60	2,500
Total					5,258

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

II. References

The following references are 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, S.B., and Schucker, R.E. "Nutrition Labeling Formats: Performance and Preference," *Food Technology*, 45: 116–121, 1991.
2. Levy, A.S., Fein, S.B., and Schucker, R.E. "More Effective Nutrition Label Formats Are Not Necessarily Preferred," *Journal of the American Dietetic Association*, 92: 1230–1234, 1992.
3. Levy, A.S., Fein, S.B., and Schucker, R.E. "Performance Characteristics of Seven Nutrition Label Formats," *Journal of Public Policy and Marketing*, 15: 1–15, 1996.
4. Lando, A.M. and Labiner-Wolfe, J. "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, available at *http://www.fda.gov/Food/LabelingNutrition/ReportsResearch/ucm081696.htm.*
6. U.S. Food and Drug Administration. "2008 Health and Diet Survey—Preliminary Topline Frequencies (Weighted)," 2010, available at *http://www.fda.gov/Food/ScienceResearch/ResearchAreas/ConsumerResearch/ucm193895.htm.*
7. Li, F., Miniard, P.W., and Barone, M.J. "The Facilitating Influence of Consumer Knowledge on the Effectiveness of Daily Value Reference Information," *Journal of the Academy of Marketing Science*, 28: 425–436, 2000.
8. Levy, L., Patterson, R.E., Kristal, A.R., and Li, S.S. "How Well Do Consumers Understand Percentage Daily Value on Food Labels?" *American Journal of Health Promotion*, 14: 157–160, 2000.
9. Institute of Medicine. *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification.* Washington, DC: National Academies Press, 2003.

Dated: May 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–12556 Filed 5–20–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0640]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Data To Support Food and Nutrition Product Communications, as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 22, 2011.

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 "Data to Support Food and Nutrition Product Communications, as Used by the Food and Drug Administration." 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.