TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Content of labeling submissions in NDAs, ANDAs, supplemental NDAs and ANDAs, and annual reports	Number of respondents	Number of responses per response	Total annual responses	Average burden per response	Total hours
	500	11.50	5,750	1.25	7,187.50

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

Dated: May 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–12825 Filed 5–29–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0495]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study on Consumer Responses to Nutrition Facts Labels With Various Footnote Formats and Declaration of Amount of Added Sugars

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 July 1, 2013.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title ''Experimental Study on Consumer Responses to Nutrition Facts Labels with Various Footnote Formats and Declaration of Amount of Added Sugars.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@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.

Experimental Study on Consumer Responses to Nutrition Facts Labels with Various Footnote Formats and Declaration of Amount of Added Sugars—(OMB Control Number 0910–New)

I. Background

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 to 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, the 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 a description of percent Daily Value, a succinct statement about daily caloric intake, a general guideline for interpreting percent Daily Values, or a footnote about nutrients whose daily intake should be limited.

This study will also explore how declaring the added sugars content of foods might affect consumers' attention to and understanding of the sugars and calorie contents and other information on the Nutrition Facts label. FDA received numerous comments regarding the declaration of added sugars in response to the 2007 ANPRM even though the Agency did not ask any

questions regarding the declaration of added sugars. The Agency is not aware of any existing consumer research that has examined this topic and is therefore interested in using this study to enhance its understanding of how consumers might currently perceive and use this new information if it is presented on the Nutrition Facts label.

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 Nutrition Facts label images from a set of food labels that will be created for the study. The label formats will vary in the presence or absence of: (1) A footnote describing percent Daily Value (''The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet''); (2) a footnote indicating those nutrients whose daily intake should be limited (i.e., saturated fat, trans fat, cholesterol, sodium, and sugars); (3) a footnote including a general guideline for interpreting percent Daily Values, such as, ''5% or less is a little, 20% or more is a lot''; (4) a footnote including a succinct statement about daily caloric intake (e.g., ''2,000 calories a day is used for general nutrition advice, but people have different calorie needs''); and (5) a declaration for added sugars. All label images will be mockups resembling Nutrition Facts labels that may be found in the marketplace. Images will show product identity (e.g., yogurt or frozen meal), 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 healthfulness; (2) ability to use the Nutrition Facts label in tasks, such as comparing two products, identifying a product's nutrient contents, and evaluating the levels of vitamin, mineral, and other nutrient content of a product; 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 through labeling, consumer education, or both. 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, and how to better educate people in using the Nutrition Facts label. Results of the study will not be used to develop population estimates.

In the **Federal Register** of May 31, 2012 (77 FR 32120), FDA published a 60-day notice requesting public comment on the proposed collection of information. The Agency received 19 written responses containing multiple comments. Many comments outlined detailed technical feedback regarding the design of a draft questionnaire that was associated with a **Federal Register** notice published on December 29, 2011 (76 FR 81948). That notice was officially withdrawn in a subsequent **Federal Register** notice published on May 31, 2012 (77 FR 32122), and all documentation associated with the withdrawn notice is considered obsolete. The Agency also received comments related to the declaration of added sugars on the Nutrition Facts label. To the extent that comments about added sugars declarations raised regulatory, policy, and nutrition science issues, the Agency notes that such comments are not directly related to the proposed consumer research and are therefore not addressed in this notice.

The responses included in this notice address comments that pertain directly to the currently proposed collection of information. Specifically, this notice addresses those comments that relate to the topics on which the FDA invited comments in the **Federal Register** of May 31, 2012: (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.

(Comment 1) While a number of comments supported the proposed collection of information, a number of comments also questioned whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility. Among the issues raised with regard to whether the information is necessary for the proper performance of FDA's functions was whether the Agency has sufficient justification to require, or the ability to enforce, added sugars declarations on Nutrition Facts labels. These comments discussed an uncertain relationship between added sugars and chronic health conditions, the current inability of most analytical methods to detect added sugars content in foods, and views on added sugars declarations that the Agency has historically expressed.

(Response 1) The Dietary Guidelines for Americans 2010 (2010 DGA) recommend the reduction in consumption of added sugars which currently comprise 16% of the daily energy intake. The DGA noted that ''many foods that contain added sugars often supply calories, but few or no essential nutrients and no dietary fiber.'' The current Nutrition Facts label does not permit the declaration of added sugars on the label. Section 403(q)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) provides that the Secretary of Health and Human Services may, by regulation, require other nutrients to be declared in nutrition labeling if the Secretary determines that a nutrient will provide information regarding the nutritional value of a food that will assist consumers in maintaining healthy dietary practices. The Agency proposes to examine added sugars declarations, along with other label modifications, in this information collection. The information gathered will have utility for the Agency as general information about consumers' current perceptions and use of information appearing on the Nutrition Facts label and will inform future education efforts. The study may also inform the Agency about what changes it should consider related to the Nutrition Facts label. The Agency's proposal to conduct consumer research on added sugars declarations does not constitute a proposal for changes in which nutrients must or may be declared on the Nutrition Facts label. Comments concerning regulatory, policy, and nutrition science related to added sugars declarations are outside the scope of this proposed collection of information. If and when the Agency

proposes changes to the current format and content of the Nutrition Facts label, the public will be invited to comment on the relevant regulatory, policy, and nutrition science questions. Further, the concerns raised by the comments would not necessarily preclude the Agency from proposing changes to the Nutrition Facts label that may be informed by this study.

(Comment 2) A number of comments offered suggestions about additional consumer research or raised policy or nutrition science matters for consideration. Specifically, one comment recommended that FDA evaluate the effects of labels that show only added sugars and juice sugars, instead of showing total sugars. The same comment also suggested that FDA test consumers' understanding of how much sugar a food contains when amounts are provided in teaspoons as opposed to grams. Two comments urged FDA to set a daily value for sugars, added sugars, or both. One comment urged FDA to evaluate the effect on consumers of distinguishing between whole versus refined fiber on the Nutrition Facts label, as recommended by the Institute of Medicine. One comment suggested identifying a disqualifying level of total or added sugars that would make a product ineligible to have a health claim on its packaging because certain foods that are high in sugars may bear health claims and mislead consumers to think a product is healthier than it is. One comment noted that certain juice products may have more added sugars than, but the same or lower level of total sugars as, other juice or dried fruit products. The comment claimed that highlighting added sugars would minimize the health benefits of those products that contain more added sugar but lower total sugar than other juice or fruit products.

(Response 2) These comments are outside of the scope of the proposed collection of information described in the 60-day notice and therefore are not addressed here.

(Comment 3) Multiple comments cited the importance of evaluating consumer responses to potential changes to the Nutrition Facts label and how consumer understanding of the nutritional attributes of packaged foods may be affected by these changes, and therefore supported the proposed study.

(Response 3) The Agency agrees with these comments.

(Comment 4) Multiple comments noted the importance of educating consumers about how to make positive food choices, rather than relying solely on Nutrition Facts labeling as a method of assisting consumers in maintaining healthy dietary practices.

(Response 4) FDA agrees that consumer education is important to help consumers understand how to make healthy dietary choices, and has been conducting and sponsoring a variety of education efforts through its Web site (e.g., Refs. 9 to 14) and other programs such as the ''Spot the Block'' campaign (Refs. 13 and 14). The results of the proposed study will provide the Agency additional information to help guide future consumer education about how to use food labels to make healthy dietary choices.

(Comment 5) One comment noted that while Internet-administered questionnaires minimize burden on respondents and possible administration errors, expedite the timeliness of data collection and processing, and are less intrusive and less costly than other modes of questionnaire administration, there are also drawbacks to this mode of survey administration. Two comments noted limitations pertaining to online consumer panels, specifying that because panel-based samples are not representative of the general U.S. population, the results of the study cannot be applied to all U.S. consumers. One comment questioned why the Agency has not elected to restrict the research to respondents who shop for food or who read Nutrition Facts labels. The comment suggested that the study should screen for consumers who have a high probability of seeing Nutrition Facts labels or who actually consume or purchase the types of food products to be included in the proposed study.

(Response 5) The Agency acknowledges the limitations of Internet-administered research and the constraints associated with using samples drawn from online consumer panels. We note that the study is a controlled experimental study that would employ random assignment and is intended to examine causal relationships between certain label format modifications and respondents' reactions to the modifications. The study is not a survey that aims to generate population estimates of how many consumers would react to different modifications in particular ways. Because the study is not intended to generate population estimates, the Agency disagrees that the limitations of the sample would preclude meaningful conclusions about potential effects of the label format modifications, or that the study should be limited to participants characterized by particular label use or product use habits. In describing the data collected and results of the analysis, FDA will clearly acknowledge that the experimental data do not provide nationally representative population estimates of consumer understanding, behaviors, or perceptions, but nevertheless provide valid and quantitative estimates of differences across experimental conditions.

(Comment 6) Three comments expressed concern about asking respondents to judge the overall healthfulness of the products they view in the study. These comments noted that consumers' definitions of healthfulness may or may not be consistent with FDA's regulatory definition of healthy. Because different consumers are likely to define ''healthier'' using different criteria, one comment suggested providing a definition of ''healthier'' to ensure that all respondents are using the same definition. The comment asserted that because respondents may use idiosyncratic bases for responding to such questions, it is unclear how the results can be compared across respondents. The same comment noted similar concerns about asking participants to report their perceptions of how much sugar a product contains, how well they understand the content of a given label, or how likely they would be to include a given product as part of their diet.

(Response 6) The Agency disagrees with these comments. These comments fail to account for the randomized, controlled, experimental design of the proposed research and mischaracterize the primary function of the selected measures in the context of the proposed study. The proposed study is not a cross-sectional survey, but rather an experiment. Relative to cross-sectional surveys, properly designed experiments are better able to determine causal effects attributable to the independent variables, such as the nutrient levels shown on the Nutrition Facts label, which have been systematically varied by the experimenter. As an experiment, the focus is on the differences observed between treatment groups (e.g., those who see labels with format modifications) and control groups (e.g., those who see labels in the current Nutrition Facts format). Because participants will be randomly assigned to experimental conditions that systematically vary in certain respects, idiosyncratic variations, such as individuals' understanding of healthfulness and different ways of judging the relative nutrient content of various foods, are likely to be distributed evenly across conditions. As a result, differences in outcomes that

may be observed between conditions would most likely be due to experimental factors as opposed to individual idiosyncrasies.

Thus, the Agency has proposed an experimental method for understanding the causal effects of added sugars declarations on consumer responses to Nutrition Facts labels. The measurement approaches selected for the proposed study are well-established and have been employed in numerous peer-reviewed scientific publications (see, for example, Refs. 1 to 3; 15 to 24). In studies such as these, participants demonstrate their practical understanding of the nutritional information about selected foods through their completion of selected dietary tasks, such as comparing the healthfulness of different food items or judging how healthful they think a product is. Importantly, research has demonstrated that if consumers perceive that a product is healthful, they may be more likely to purchase or consume more of that food, and may be more likely to view that food as possessing other positive attributes that it may not objectively have (Refs. 25 and 26). Thus, consumer judgments of product healthfulness as well as calorie and nutrient levels will serve as vital indicators of how various Nutrition Facts information and formats may assist consumers in identifying healthful food products and in comparing the calorie and nutrient contents of different food products. In turn, data derived from this research will assist the Agency in determining directions for future research and educational activities.

For the purposes of this study, it is not necessary to provide consumers with a specific definition of ''healthier.'' The study aims to examine what consumers may infer from the Nutrition Facts labels based on their own interpretations, not to examine definitions of ''healthy'' or ''healthier'' according to regulatory or scientific perspectives. Evaluating potential effects of added sugars declarations on consumers with a diverse range of nutrition knowledge using a randomized, controlled, experimental study will provide useful information about consumers' current perceptions and use of information appearing on the Nutrition Facts label and will inform future education efforts.

While random assignment is the most robust method for significantly reducing the plausibility of individual difference explanations for observed differences between treatment and control conditions, we also plan to collect measures of individual characteristics that will allow for some statistical control of potential confounders. The measurement of these additional covariates (e.g., how often people eat and purchase the categories of foods included in the study, people's typical label use frequency, demographic characteristics, etc.) will further enhance the study's explanatory power.

(Comment 7) One comment questioned the utility of collecting participants' ratings of a given label's usefulness and helpfulness for making various dietary judgments.

(Response 7) The measures to which this comment refers (e.g., asking respondents to rate on a scale from 1 = ''not at all'' to 5 = ''very'' how hard it is to understand the information shown on the label) are indicators of consumers' attitudinal responses toward the label formats. FDA draws a distinction between these types of attitudinal measures and behavioral performance measures (i.e., how well consumers use a label format for completing a specific task, such as judging healthfulness and identifying nutritional characteristics of a product). The Agency has typically considered behavioral performance measures to be more consequential than ratings of label usefulness, understandability, and helpfulness. Nevertheless, the Agency also collects these ratings because it is possible that inferior ratings of usefulness, understandability, and helpfulness could be indicative of a potential problem with a particular label modification or label format. It is therefore important to collect these kinds of ratings.

(Comment 8) Some comments asserted that including added sugars declarations would detract from consumers' focus on other nutrition information, specifically total calories. Related comments noted that consumers would be confused or misled by added sugars declarations. A few comments proposed that consumer research should focus on exactly how consumers understand the term ''added sugars,'' the particular meanings that consumers attach to various kinds of sugars, and the health effects that consumers associate with added sugars. Two comments asked if FDA plans to explore whether including ''added sugar'' and ''naturally occurring sugar'' on the Nutrition Facts label under total sugars would increase consumer understanding of products' nutritional attributes and healthfulness. One comment requested that the Agency establish definitions that differentiate between added sugars and naturally occurring sugars before conducting consumer research. These comments expressed concern that consumer understanding about sugars does not match definitions that might be endorsed by various regulatory or scientific entities. Another comment suggested that the Agency study how information about added sugars in ingredient listings might affect attention to and understanding of information in the Nutrition Facts.

(Response 8) The Agency agrees that the questions raised in these comments would be suitable for future research. The purpose of the currently proposed study is to provide the Agency with an initial understanding of potential consumer reactions to added sugars declarations on Nutrition Facts labels, information that would, in turn, help guide education efforts. In response to comments that raised concerns about the potential for added sugars declarations to affect consumer attention to and perceptions of other nutritional attributes presented in Nutrition Facts labels, FDA notes that the proposed experimental design is intended to address this possibility through the collection of respondent judgments of the nutritional attributes and overall healthfulness of foods that contain varying levels of calories, fat, and other nutrients. Additionally, as previously noted, FDA recognizes the importance of evaluating the potential effects of any proposed Nutrition Facts label modifications on consumer understanding. The proposed study will therefore include systematically varied experimental conditions and controls, and will employ appropriate measures to assess how various format modifications may affect consumer understanding of the Nutrition Facts label information. Due to resource limitations, the study cannot accommodate additional experimental conditions to evaluate consumer responses to ingredient listings. The study will, however, collect information about what names of various types of added sugars respondents recognize that might appear in ingredient listings.

(Comment 9) One comment objected to asking consumers about health effects (e.g., heart disease and diabetes) that consumers would associate with consuming a particular food product. The comment argued that consumer research questions should align with FDA's regulations regarding health claims, regulations which preclude suggestions that food substances may prevent, treat, or cure any particular disease or condition.

(Response 9) FDA disagrees with these comments. Several health conditions have been linked to dietary quality, and dietary quality is

influenced by consumer perceptions and food choices. Regardless of FDA's regulations, consumers often make their own inferences about the relationships between food substances and the risk of various health conditions from labeling information. Rigorous and informative consumer research that aims to assess consumer understanding of labeling information typically accounts for the broader inferences consumers may make about food products, although the particular health conditions of interest in a particular consumer research study may vary (as evident in Refs. 1 to 3 and 15 to 24). In order to assess the extent to which consumers may infer broader health outcomes from nutrition information on the label, the study will ask respondents to judge whether people concerned about conditions such as osteoporosis or cancer should include a particular food item in their diet.

(Comment 10) One comment suggested that, instead of asking respondents if they use Nutrition Facts labels ''To see if something said in advertising or on the package is actually true,'' the item be reworded to say ''To confirm a statement in advertising or on the package,'' arguing that the former implies that inconsistency may exist between advertising and labeling statements and that consumers can independently verify label declarations.

(Response 10) The comment did not provide any data to support this rationale, and the Agency is not aware of any evidence to suggest that consumers interpret the survey item in question in the manner described in the comment. Nevertheless, this comment is no longer applicable to the proposed study because the item in question has been removed in order to prioritize collection of other information that is considered more relevant to the objectives of the current study.

(Comment 11) One comment stated that if the Agency is intending to include added sugars information on the Nutrition Facts label by indenting the phrase ''Added Sugars'' below where the declaration for ''Sugars'' appears, it is possible that consumers may not understand that added sugars are a subset of the amount of sugars. The comment suggested that the Agency study consumer responses to a Nutrition Facts format that adds the word ''total'' to the sugars declaration, so that this alternative format can also be evaluated in the proposed consumer research, noting that it might be beneficial to test more than one added sugars declaration format.

(Response 11) The Agency agrees with this comment and will plan to include an alternative label format that adds the word ''total'' to the sugars declaration in the proposed research. Thus, the study will include two formats for declaring ''Added Sugars'' on the Nutrition Facts label: One format in which the declaration is indented below a ''Sugars'' declaration, and one format in which the declaration is indented below a ''Total Sugars'' declaration.

(Comment 12) One comment suggested that the Agency use the cognitive interviews to ask consumers their understanding of the phrase ''added sugars'' as it appears on some of the experimental Nutrition Facts formats. The comment also recommended that the number of cognitive interviews be sufficient to assess the level of comprehension of this terminology.

(Response 12) The Agency plans to conduct in-person cognitive interviews with participants of various ages, educational levels, and household incomes. The Agency agrees that it may be useful to ask cognitive interview participants about their understanding of the phrase ''added sugars'' and will include questions about this topic in all of the cognitive interviews that are conducted for the proposed study. Given that the primary purpose of the cognitive interviews is to assist with refinement of the questionnaire, the Agency does not agree that the number of cognitive interviews should be modified for assessing comprehension of added sugars terminology.

(Comment 13) One comment suggested that the proposed sample size for the study might be larger than necessary, unless the Agency expects to conduct subgroup analyses within experimental conditions.

(Response 13) As the comment noted, the Agency confirms that allowing for subgroup analyses constitutes one of the reasons for the proposed sample size. Another reason for the proposed sample size is to allow for assessment of interactions between the various experimental factors (e.g., label format × food category × nutrition profile). Indeed, the ability to detect interactions is of equal, if not more, importance to fulfilling the Agency's information objectives than the ability to detect only the main effects of experimental factors such as label format, food category, or nutrition profile.

(Comment 14) One comment suggested two alternative definitions for percent Daily Value: (1) ''The Percent Daily Value tells you how much of a day's worth of a nutrient one serving of this food provides''; and (2) ''The Percent Daily Value tells you how much of a day's worth of a nutrient you would get from one serving of this food.''

(Response 14) Due to resource limitations, the Agency is not able to test the alternative definitions of percent Daily Value suggested in this comment.

(Comment 15) One comment objected to asking respondents to evaluate whether a product is an ''excellent source'' of or ''low'' in a particular nutrient relative to footnote messages that indicate that 5% or less of the Daily Value for a nutrient is ''low'' or ''a little'' and 20% or more of the Daily Value is ''high'' or ''a lot.'' The comment raised concerns that consumers may not interpret or apply such footnote messages as FDA intends.

(Response 15) FDA agrees that some consumers may not interpret or apply a particular footnote message as FDA intends. That is one reason for asking respondents to characterize the vitamin and nutrient content of selected products. Collecting information about differences between consumer interpretations of information versus FDA definitions will help guide FDA's ongoing informational efforts to provide consumer guidance on how to use percent Daily Values.

(Comment 16) Two comments suggested that FDA test effects of including ''high'' and ''low'' text next to the appropriate nutrients on the NF label in accordance with the 5% and 20% guideline levels. One of these comments also suggested certain nutrients and their amounts be printed in red ink or against a red background, in conjunction with the word ''high'' being printed in red and positioned between the amount of the nutrient and the percent Daily Value.

(Response 16) The Agency has studied the use of adjectives such as ''high'' and ''low'' on Nutrition Facts labels in prior research (Refs. 1 and 3). That research found that Nutrition Facts formats that included adjectives did not significantly improve respondents' accuracy in dietary judgment tasks relative to Nutrition Facts formats that did not include such adjectives. Specifying a particular color scheme for selected content in the Nutrition Facts label or adding amount descriptors next to certain nutrients are beyond the scope of this study.

(Comment 17) One comment suggested testing alternative statements for recommended caloric intake, including statements of calorie ranges; statements indicating that calorie requirements change with age, height, and activity level; and statements suggesting consumers check their own caloric needs on a Government run Web site (e.g., *www.choosemyplate.gov*). A proposed sample statement offered was: ''The recommended daily intake for an

average adult is 2,000 calories. See *www.xxx.gov* for individual calorie needs based on gender, age and activity level.''

(Response 17) Due to resource limitations, the Agency is not able to test the alternative statements for recommended caloric intake suggested in this comment. In addition to calorie requirements changing with age, height, and activity level, as the comment stated, calorie requirements also vary according to a number of other factors, including body composition (percentages of lean body mass and body fat), basal and resting metabolic rate, ambient temperature, genetic factors, whether a woman is pregnant or lactating, and others. An accurate label statement explaining how calorie needs vary would be too lengthy and complex for inclusion on Nutrition Facts labels. Using the phrase ''recommended daily intake'' for calorie requirements, as the comment suggests, could also be problematic, since 2,000 calories is not a recommended intake level, but is rather used as the basis for setting Daily Reference Values (DRVs) for nutrients having DRVs that are based on caloric intake. Finally, there are many Web sites that provide information on estimating individual calorie needs. The question of whether it would be suitable for the Nutrition Facts label to single out any one particular Web site is beyond the scope of the 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	Total hours
Cognitive interview screener	72	1	72	0.083 (5 min.)	6
Cognitive interview	9	1	9	1	9
Pretest invitation	1,000	1	1,000	0.033 (2 min.)	33
Pretest	150	1	150	0.25 (15 min.)	38
Survey invitation	40,000	1	40,000	0.033 (2 min.)	1,320
Survey	10,000	1	10,000	0.25 (15 min.)	2,500
Total					3,906

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

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, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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2. Levy, A. S., S. B. Fein, and R. E. Schucker, ''More Effective Nutrition Label Formats are not Necessarily Preferred,'' *Journal of the American Dietetic Association,* vol. 92, pp. 1230–1234, 1992.
3. Levy, A. S., S. B. Fein, and R. E. Schucker, ''Performance Characteristics of Seven Nutrition Label Formats,'' *Journal of Public Policy and Marketing,* 15: 1–15, 1996.
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6. U.S. Food and Drug Administration, ''2008 Health and Diet Survey—Preliminary Topline Frequencies (Weighted),'' 2010, available at *http://www.fda.gov/Food/FoodScienceResearch/ConsumerBehaviorResearch/ucm193895.htm.*
7. Li, F., P. W. Miniard, and M. J. Barone, ''The Facilitating Influence of Consumer Knowledge on the Effectiveness of Daily Value Reference Information,'' *Journal of the Academy of Marketing Science,* vol. 28, pp. 425–436, 2000.
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9. U.S. Food and Drug Administration, ''A Key to Choosing Healthful Foods: Using the Nutrition Facts on the Food Label,'' available at *http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079449.htm.*
10. U.S. Food and Drug Administration, ''The Food Label and You—Video,'' available at *http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm275409.htm.*
11. U.S. Food and Drug Administration, ''How to Understand and Use the Nutrition Facts Label,'' available at *http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm274593.htm.*
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Dated: May 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0297]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prevention of Salmonella Enteritidis in Shell Eggs During Production—Recordkeeping and Registration

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 July 1, 2013.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0660. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, 301–796–5733, *domini.bean@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.

Prevention of *Salmonella* Enteritidis in Shell Eggs During Production—Recordkeeping and Registration Provisions—21 CFR 118.10 and 118.11 (OMB Control Number 0910–0660)—Extension

Shell eggs contaminated with *Salmonella* Enteritidis (SE) are responsible for more than 140,000 illnesses per year. The Public Health Service Act (PHS Act) authorizes the Secretary to make and enforce such regulations as ''are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States . . . or from one State . . . into any other State'' (section 361(a) of the PHS Act). This authority has been delegated to the Commissioner of Food and Drugs. Under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(4)), a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act.

On July 9, 2009, FDA published in the **Federal Register** a final rule that established a regulation part 118 (21 CFR part 118) entitled ''Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation'' (74 FR 33030) (the Shell Eggs final rule''). Part 118 requires shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation, and requires these producers to maintain records concerning their compliance with the rule and to register with FDA. As described in more detail with regard to each information collection provision of part 118, each farm site with 3,000 or more egg-laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, must refrigerate, register, and keep certain records. Farms that do not send all of their eggs to treatment are also required to have an SE prevention plan and to test for SE.

Section 118.10 of FDA's regulations (21 CFR 118.10) requires recordkeeping for all measures the farm takes to prevent SE in its flocks. Since many existing farms participate in voluntary egg quality assurance programs, those respondents may not have to collect any additional information. Records are maintained on file at each farm site and examined there periodically by FDA inspectors.

Section 118.10 also requires each farm site with 3,000 or more egg-laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, and does not have all of the shell eggs treated, to design and implement an SE prevention plan. Section 118.10 requires recordkeeping for each of the provisions included in the plan and for plan review and modifications if corrective actions are taken.

Finally, § 118.11 of FDA's regulations (21 CFR 118.11) requires that each farm covered by § 118.1(a) register with FDA using Form FDA 3733. The term ''Form FDA 3733'' refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at *http://www.access.fda.gov.* The Agency strongly encourages electronic registration because it is faster and more convenient. The system the Agency has developed can accept electronic registrations 24 hours a day, 7 days a week. A registering shell egg producer will receive confirmation of electronic registration instantaneously once all the required fields on the registration screen are completed. However, paper registrations will also be accepted. Form