Estimated Total Annual Burden Hours: 330,000

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

ACF specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–8589 Filed 4–10–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0221]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study on Consumer Responses to Labeling Statements on Food Packages

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by May 11, 2012.

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 Labeling Statements on Food Packages.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, II, 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.

Experimental Study on Consumer Responses to Labeling Statements on Food Packages—(OMB Control Number 0910–NEW)

I. Background

The Nutrition Labeling and Education Act requires almost all packaged foods to bear nutrition labeling in the form of the Nutrition Facts label. The law also allows manufacturers to provide other nutrition information on labels in the form of various types of statements, including claims, as long as such statements comply with the regulatory limits that govern the use of each type of statement. There are three types of claims that the food industry can voluntarily use on food labels: (1) Health claims, (2) nutrient content claims (e.g., ''Low fat''), and (3) structure/function claims (e.g., ''Calcium builds strong bones.''). Although the different types of claims are regulated differently, they all must be truthful and not misleading (Ref. 1).

With the increased public interest in identifying healthier foods, U.S. food processors have been adding nutritional information in the form of nutrition symbols to food labels in addition to claims. Examples of nutrition symbols that have been used or suggested include nutrient-specific disclosures (e.g., ''Guideline Daily Amounts'') (Ref. 2), calorie declarations (Ref. 3), summary product rating (e.g., ''Smart Spot'') (Ref. 4), a hybrid summary indicator with nutrient-specific disclosure (e.g., ''Sensible Solution: Good Source of Calcium, Good Sources of 8 Vitamins and Minerals'') (Ref. 5), the Facts-Up-Front icon, with and without positive nutrients (Ref. 6), and the symbol recommended by the Institute of Medicine (Ref. 7). Claims related to non-nutritional product characteristics are also used in food labeling. The claims may feature, among other things, statements about how foods are grown or made (e.g., ''Organic'' and ''All Natural'') or absence of a substance (e.g., ''Gluten-free'').

Many consumers use claims and the Nutrition Facts label in food choice decisions (Refs. 8 through 10). While some products carry only a single labeling statement (e.g., either one claim or one symbol) on their packages, many products carry two or more labeling statements. In addition, on the same package the attributes of one statement may differ from those of other statements in terms of featured nutrient, type of claim, framing of statement, nature of statement, and presentation of statement. For example, a package may display one or more statements such as symbols relating to nutrition content, statements in words relating to the presence of certain nutrients, statements in words relating to the absence of other nutrients, statements in words describing the health benefits of consuming foods containing or not containing certain nutrients, and statements in words describing how the product was produced. Moreover, all of those symbols and statements are distributed in various places on the package in different font sizes and colors.

There exists a large body of literature on the impacts of different types of labeling statements on consumer perceptions and choices of products (Refs. 11 and 12). The majority of the research, including the consumer research that the Agency has previously conducted (Refs. 13 and 14), has focused on single labeling statements by eliciting study participants' reactions to variants of a given statement. An advantage of this research approach is that it helps isolate the effects of individual statements and avoid potential confounding effects caused by the presence of other statements. A disadvantage of this research approach, however, is that it does not necessarily reflect the labels consumers see in the marketplace. In particular, the existing

literature provides little information about how the coexistence of two or more different labeling statements affects product perceptions and choices. This information, however, is critical for understanding the roles played by labeling statements in dietary decisions.

Research suggests consumer product perceptions and purchase decisions can be influenced by labeling statements and different labeling statements may have different influences (Refs. 11 through 14). Therefore, FDA, as part of its effort to promote public health, proposes to use this study to explore consumer responses to food labels that bear multiple labeling statements. Specifically, the study plans to examine: (1) Consumer responses to food labels that exhibit various combinations of the number and type of statements, (2) whether and how consumer responses to one label characteristic may be affected by the other characteristic (i.e., the interactions between different characteristics of labeling statements), and (3) whether and how labeling statements affect consumers' use of the Nutrition Facts label.

The proposed collection of information is a controlled randomized experimental study. The study will use a 15-minute Web-based survey to collect information from 4,000 English-speaking adult members of an online consumer panel maintained by a contractor. The study will aim to produce 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 two label images from a set of food labels that will be created for the study. These images will be systematically varied in the following aspects: (1) Number of statements (ranging from none to three); (2) featured nutrient and food product (fat—snack bar, sodium—chips, or fiber—breakfast cereal); (3) type of statement (text such as ''Supports Cardiovascular Functioning'' or graphic, specifically the Facts-Up-Front icons and one of the icon concepts proposed by the Institute of Medicine) (Refs. 13 and 14); and (4) nature of featured product attribute (such as ''Supports the Immune System'' or ''All Natural''). With regard to claims, the study will focus on examples of nutrient content claims and structure/function claims that can be found on many food packages (Ref. 15). All label images will be mockups resembling food labels that may be found in the marketplace. Images will show product identity (e.g., tortilla chips) but not any real or fictitious brand name. The study will provide interested participants access to the Nutrition Facts label but not together with a product image.

The survey will ask its participants to view label images and answer questions about their perceptions and reactions related to the viewed product and label. Product perceptions (e.g., healthfulness, potential health benefits, levels of nutrients, and taste) and label perceptions (e.g., helpfulness and credibility) will constitute the measures of responses in the experiment. To help understand the data, the survey will also collect information about participants' background, such as familiarity with and consumption, purchase, and perception of the categories of food included in the study; awareness and knowledge of nutrients; dietary interests; motivation regarding label use and health literacy; and health status and demographic characteristics.

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 enrich the Agency's understanding of how multiple claims and other labeling statements on food packages 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.

In the **Federal Register** of April 13, 2011 (76 FR 20675), FDA published a 60-day notice requesting public comment on the proposed collection of information. The Agency received four responses to the notice. One of the responses was outside of the scope of the proposed collection of information described in the 60-day notice and is not addressed here. The remaining three responses contained multiple comments. These comments, and the Agency's responses, are discussed in the following paragraphs.

(Comment 1) Two comments suggested that FDA provide mock stimuli for public comment prior to initiating the study.

(Response) We appreciate the suggestion for the Agency to provide the experimental stimuli for public comment prior to initiating the study. Per the PRA, a copy of the proposed experimental stimuli is provided in the Appendix of the supporting document.

(Comment 2) One comment suggested that the study include questions to probe how non-misleading nutrient content, health, and structure/function claims may improve consumers' understanding of a product's nutritional attributes.

(Response) We agree and have included measures to assess how participants' understanding of a product's nutritional attributes may be affected by non-misleading claims.

(Comment 3) Two comments expressed concerns about four questions proposed in the draft questionnaire. Two of the questions of concern asked if participants had ever heard or read that certain foods (unnamed) may help lower the risk of seven different types of health problems, such as cancer, diabetes, and others. The third and fourth questions of concern asked whether specific nutrients (e.g., calcium, potassium, etc.) or a particular food product, respectively, might help reduce the risk of the same health problems asked about in the other two questions. Both comments suggested that such questions would demonstrate that ''consumers misinterpret structure function claims as health claims'' and argued that such a demonstration would be inconsistent with the stated purpose of the information collection.

(Response) FDA does not agree that the proposed questions on participants' prior knowledge of foods' health benefits and inferences from reading a label would bias the study toward health claims rather than structure/function claims. Since label inferences can be affected by what consumers already know or believe about a food, the prior knowledge questions are included to help understand study participants' reactions to labeling statements. The question about perceived health benefits of a product is one of the most important measures of label inferences. The Agency's previous research has shown that consumer inferences of the health benefits of a product do not necessarily vary between types of labeling statements (i.e., health claims, structure/function claims, and nutrient content claims). Hence, this question is not expected to produce erroneous data with respect to inferences about structure/function claims.

(Comment 4) One comment suggested that FDA consider including an experimental condition in which participants would view a label bearing up to three different labeling statements because consumers are routinely exposed to this amount of information on food packages. In the originally proposed design, FDA included label manipulations involving only up to two different labeling statements.

(Response) We agree with the comment and have revised the study to include experimental conditions containing up to three labeling statements on a label.

(Comment 5) One comment suggested including an assessment of how the

various labeling statements affect whether participants intend to purchase the product or not.

(Response) As we proposed in the draft questionnaire, we will include a question about purchase intention.

(Comment 6) One commenter noted that prior research has shown that the appearance of packaging and statements on the front of the package can increase the likelihood of consumers using the Nutrition Facts label.

(Response) FDA agrees that information about consumers' use of the Nutrition Facts label is important and plans to record and analyze how likely the study's participants are to consult the Nutrition Facts label when viewing claims and other statements on the front label of a product.

(Comment 7) One comment questioned the relevance of asking participants to rate the safety or trustworthiness of a product based on the label information they view.

(Response) Although the label content of a product may not be intended to influence consumer assumptions regarding the safety of a product, prior research has demonstrated that such influence may occur (Ref. 16). Therefore, it would be useful to understand whether similar reactions happen in a multiclaim context. Nevertheless, the products that the proposed study plans to include (breakfast cereal, chips, and snack bars) are generally not associated with safety issues that may lead to foodborne illness or other safety hazards. Therefore, the study will omit the proposed question on perceived product safety. On the other hand, the Agency has determined that it is still important and relevant to elicit study participants' perceptions of the trustworthiness of various labeling statements (not foods, as stated in the comment), especially when these statements feature different nutrients or product benefits. Thus, the study will keep the proposed question on perceived trustworthiness of the label.

(Comment 8) One comment suggested that the study ask about participants' interest in nutrients for which there is concern of inadequate intake among Americans. The comment recommended replacing Vitamin D and omega-3 fatty acids for Vitamins A and C, as proposed in the previous draft questionnaire.

(Response) We agree with the comment and have incorporated the suggestion in the revised questionnaire.

(Comment 9) One comment suggested that a plausible distractor or wrong choice be included in the question about the nutrients participants try to limit or increase in their diet to test the validity of the responses.

(Response) We disagree with the comment. Our previous surveys indicate respondents can provide valid responses to these questions (for example, Ref. 17). Furthermore, we are concerned that the validity of the responses would suffer if a distractor or wrong choice is included because participants may be confused by the presence of such options in the question.

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 32,000 invitations, each taking 2 minutes (0.033 hour) to complete, will need to be sent to the consumer panel to have 4,000 of its members complete a 15-minute (0.25 hour) questionnaire. The total for the survey activities is 2,056 hours (1,056 hours + 1,000 hours). Thus, the total estimated burden is 2,174 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	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive interview screener	72	1	72	0.083 (5 minutes)	6
Cognitive interview	9	1	9	1 hour	9
Pretest invitation	1,600	1	1,600	0.033 (2 minutes)	53
Pretest	200	1	200	0.25 (15 minutes)	50
Survey invitation	32,000	1	32,000	0.033 (2 minutes)	1,056
Survey	4,000	1	4,000	0.25 (15 minutes)	1,000
Total					2,174

[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 (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register.**)

1. U.S. Food and Drug Administration, ''Claims That Can Be Made for Conventional Foods and Dietary Supplements,'' September 2003. Available at *http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm111447.htm.*

2. Kellogg's, ''How to Read a Nutrition Label,'' 2010. Available at *http://www.kelloggs.com/en_US/the-benefits-of-cereal/how-to-read-a-nutrition-label.html.*

3. PepsiCo, ''Nutrition Labeling,'' 2010. Available at http://www.pepsico.com/Purpose/Human-Sustainability/Nutrition-Labeling.html.

4. Schmit, J., ''PepsiCo Labels Some of Its Snacks 'Smart,' '' *USA Today,* September 2, 2004. Available at *http://www.usatoday.com/money/industries/food/2004–09–02-smart-spot_x.htm.*

5. Kraft Foods, ''Sensible Solution,'' 2010. Available at *http://www.kraftrecipes.com/kf/HealthyLiving/SensibleSolution/SensibleSolution_Landing.aspx.*

6. FactsUpFront.org, ''Facts Up Front,'' 2011. Available at *http://factsupfront.com/.*

7. Institute of Medicine, ''Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices,'' 2011. Available at *http://www.iom.edu/Reports/*

2011/Front-of-Package-Nutrition-Rating-Systems-and-Symbols-Promoting-Healthier-Choices.aspx.

8. Centers for Disease Control and Prevention, ''2005–2006 National Health and Examination Survey Questionnaire, Diet Behavior and Nutrition section,'' Unpublished results of questions DBQ.750 and DBQ.780. Questionnaire available at *http://www.cdc.gov/nchs/data/nhanes/nhanes_05_06/sp_dbq_d.pdf.*

9. U.S. Food and Drug Administration, ''2008 Health and Diet Survey,'' March 20, 2010. Available at *http://www.fda.gov/Food/ScienceResearch/ResearchAreas/ConsumerResearch/ucm193895.htm.*

10. Food Marketing Institute, ''2009 U.S. Grocery Shopper Trends Survey,'' Washington, DC 2009.

11. Drichoutis, A.C., P. Lazaridis, and R.M. Nayga, ''Consumers' Use of Nutritional Labels: A Review of Research Studies and Issues,'' *Academy of Marketing Science Review,* 2006(9), 2006. Available at *http://www.amsreview.org/articles/drichoutis09-2006.pdf.*

12. Lähteenmäki, L., P. Lampila, K. Grunert, et. al, ''Impact of Health-Related Claims on the Perception of Other Product Attributes,'' *Food Policy*, 23: 230–239, 2010.

13. Labiner-Wolfe, J., C.-T. J. Lin, and L. Verrill, ''Effect of Low Carbohydrate Claims on Consumer Perceptions About Food Products' Healthfulness and Helpfulness for Weight Management,'' *Journal of Nutrition Education and Behavior*, 42(5): 315–320, 2010.

14. Roe, B., A.S. Levy, and B.M. Derby, ''The Impact of Health Claims on Consumer Search and Product Evaluation Outcomes: Evidence From FDA Experimental Data,'' *Journal of Public Policy and Marketing*, 18(1): 89–105, 1999.

15. LeGault, L., M.B. Brandt, N. McCabe, et. al, ''2000–2001 Food Label and Package Survey: An Update on Prevalence of Nutrition Labeling and Claims on Processed, Packaged Foods,'' *Journal of the American Dietetic Association*, 104(6): 952–958, 2004.

16. Kapsak, W.R., D. Schmidt, N.M. Childs, et. al, ''Consumer Perceptions of Graded, Graphic and Text Label Presentations for Qualified Health Claims,'' *Critical Reviews in Food Science and Nutrition*, 48: 248–256, 2008.

17. U.S. Food and Drug Administration, ''Health and Diet Survey: Dietary Guidelines Supplement—Report of Findings (2004 and 2005), 2008. Available at *http://www.fda.gov/Food/ScienceResearch/ResearchAreas/ConsumerResearch/ucm080331.htm.*

Dated: April 5, 2012.

David Dorsey,

Acting Association Commissioner for Policy and Planning.

[FR Doc. 2012–8699 Filed 4–10–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0315]

International Conference on Harmonisation; Draft Guidance for Industry on E2C(R2) Periodic Benefit-Risk Evaluation Report; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''E2C(R2) Periodic Benefit-Risk Evaluation Report.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance updates and combines two ICH guidances, ''E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs'' (E2C guidance) and ''Addendum to E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs'' (addendum to the E2C guidance). The draft guidance describes the format, content, and timing of a periodic benefit-risk evaluation report (PBRER) for an approved drug or biologic. The harmonized PBRER is intended to promote a consistent approach to periodic postmarket safety reporting among the ICH regions and to enhance efficiency by reducing the number of reports generated for submission to the regulatory authorities.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 11, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Regarding the draft guidance: Andrea Feight, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4494, Silver Spring, MD 20993–0002, 301–796–0152; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210. Regarding the ICH: Michelle Limoli, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 3506, Silver Spring, MD 20993–0002, 301–796–8377.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory Agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug