Services announces OHS Tribal Consultations for leaders of Tribal Governments operating Head Start and Early Head Start programs in Regions I, II, IV, and VI. The Consultation Session for Region VI will take place Friday, April 29, 2011, at the Indian Pueblo Cultural Center in Albuquerque, New Mexico, immediately following the Department of Health and Human Services Regional Consultations session. The Consultation Session for Regions I, II, and IV will take place Thursday, May 19, 2011, at the Paragon Casino Resort in Marksville, Louisiana, immediately following the United South and Eastern Tribes, Inc. 2011 Semi-annual Meeting. We are convening the OHS Tribal Consultations in conjunction with other Tribal Leader events in order to minimize the financial and travel burden for participants.

The agendas for both scheduled OHS Tribal Consultations will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the needs of American Indian and Alaska Native children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. In addition, OHS will share actions taken and in progress to address the issues and concerns raised in 2010 OHS Tribal Consultations.

Tribal leaders and designated representatives interested in submitting written testimony or proposing specific agenda topics for the Albuquerque or Marksville Consultation Sessions should contact Camille Loya at *Camille.Loya@acf.hhs.gov* at least three days in advance of the Session. Proposals should include a brief description of the topic area along with the name and contact information of the suggested presenter.

The Consultation Sessions will be conducted with elected or appointed leaders of Tribal Governments and their designated representatives [42 U.S.C.9835, Section 640(l)(4)(A)]. Designees must have a letter from the Tribal Government authorizing them to represent the Tribe. The letter should be submitted at least three days in advance of the Consultation Session to Camille Loya at (202) 205–9721 (fax). Other representatives of Tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of each Consultation Session will be prepared and made available within 90 days of the Consultation Session to all Tribal Governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Camille Loya at *Camille.Loya@acf.hhs.gov* either prior to the Consultation Session or within 30 days after the meeting.

Oral testimony and comments from the Consultation Session will be summarized in the report without attribution, along with topics of concern and recommendations. Hotel and logistical information for all Consultation Sessions has been sent to Tribal leaders via e-mail and posted on the Head Start Resource Center Web site at *http://www.headstartresourcecenter.org.*

Dated: April 6, 2011.

Ann Linehan,

Deputy Director, Office of Head Start.

[FR Doc. 2011–8999 Filed 4–12–11; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0221]

Agency Information Collection Activities; Proposed Collection; 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 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 Labeling Statements on Food Packages."

DATES: Submit either electronic or written comments on the collection of information by June 13, 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, 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.

Experimental Study on Consumer Responses to Labeling Statements on Food Packages; 21 U.S.C. 393(d)(2)(C)—(OMB 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."). There are three types of health claims: (1) Those that meet the Significant Scientific Standard (*e.g.,* "Adequate calcium and Vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis."), (2) those that are based on authoritative statements from a recognized scientific body of the U.S. government or the National Academy of Sciences (*e.g.,* "Diets containing foods that are a good source of potassium and that are low in sodium may reduce the risk of high blood pressure and stroke."), and (3) qualified health claims that are granted under enforcement discretion (*e.g.,* "Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [ ] grams of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.]"). 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 or are planned to be used on food labels include nutrient-specific disclosure (*e.g.,* "Guideline Daily Amounts") (Ref. 2), calorie declaration (Ref. 3), summary product rating (*e.g.,* "Smart Spot") (Ref. 4), and 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). 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. 6 through 8). 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 relating the health benefits of consuming foods containing or not containing certain other 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. 9 and 10). The majority of the research, including the consumer research that the Agency has previously conducted (Refs. 11 and 12), 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. 9 through 12). Therefore, the 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 characteristics of labeling statements (*i.e.,* nutrients, types of claim, framing of statement, nature of statement, and presentation of statement), (2) whether and how consumer responses to one of the characteristics may be affected by other characteristics (*i.e.,* the interactions between different characteristics of labeling statements), and (3) whether and how labeling statements affect the 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 and systematically varied in the (1) number of statements (none, one, or two); (2) featured nutrient and substance (*e.g.,* fat, sodium, sugars, fiber, whole grain, calories, antioxidant vitamins, or allergen); (3) type of statement (text or graphic, specifically the Guideline Daily Amounts nutrition symbol); (4) framing of statement ("good source of," "low," or "free"); (5) nature of statement (nutrition or method of production such as "natural"); (6) type size of statement (large or small); and (7) featured product (*e.g.,* snacks, breakfast cereals, breads, soups, or frozen meals). With regard to claims, the study will focus on examples of nutrient content claims and structure/function claims, which can be found on many food packages (Ref. 13). 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 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.,* healthiness, potential health benefits, levels of nutrients and substances, taste, and safety) 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 consumption, purchase, perception, and familiarity with a category of food; awareness and knowledge of nutrients and substances; 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.

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 106 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 3,000 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]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	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	32,000	1	32,000	2/60	1,056
Survey	4,000	1	4,000	15/60	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 (see **ADDRESSES**) 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. Nutrition at a Glance. 2010. Available at *http://www.kelloggnutrition.com/learn-about-labels/nutrition-at-a-glance.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 Products '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. 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 is available at *http://www.cdc.gov/nchs/data/nhanes/nhanes_05_06/sp_dbq_d.pdf.*
7. 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.*
8. Food Marketing Institute. 2009 U.S. Grocery Shopper Trends Survey. Washington, DC 2009.
9. Drichoutis, A.C., Lazaridis, P. and Nayga, R.M., "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.*
10. Lähteenmäki, L., Lampila, P.. Grunert, K., Boztug, Y., Ueland, Ø., Åström, A. and Martinsdóttir, E., "Impact of Health-Related Claims on the Perception of Other Product Attributes," *Food Policy,* 23: 230–9. 2010.
11. Labiner-Wolfe, J., Lin, C.-T. J. and Verrill L., "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.
12. Roe, B., Levy, A.S., and Derby, B.M., "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.
13. LeGault, L., Brandt, M.B., McCabe, N., Adler, C., Brown, A.-M., and Brecher, S., "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): 952–8, 2004.

Dated: April 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8908 Filed 4–12–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0237]

Agency Information Collection Activities; Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs

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