Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Clearance Officer.

[FR Doc. 2010–28925 Filed 11–16–10; 8:45 am]

BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–11–11AC]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 or send comments to Carol E. Walker, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS D–74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited 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) ways to enhance the quality, utility, and clarity of the 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. Written comments should be received within 60 days of this notice.

Proposed Project

Using Traditional Foods and Sustainable Ecological Approaches for Health Promotion and Diabetes Prevention in American Indian/Alaska Native Communities—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Type 2 Diabetes was rare among American Indians until the 1950s. Since that time, diabetes has become one of the most common and serious illnesses among American Indians and Alaska Natives (AI/AN). From 1994 to 2004, the age-adjusted prevalence of diagnosed diabetes doubled (from 8.5 to 17.1 per 1,000 population) among AI/ANs less than 35 years of age who used Indian Health Service healthcare services. However, dietary management and physical activity can help to prevent or control Type 2 diabetes.

In 2008, the CDC's Native Diabetes Wellness Program (NDWP), in consultation with American Indian/Alaska Native Tribal elders, issued a cooperative agreement entitled, "Using Traditional Foods and Sustainable Ecological Approaches for Health Promotion and Diabetes Prevention in American Indian/Alaska Native Communities." The Traditional Foods program seeks to build on what is known about traditional ways in order to inform culturally relevant, contemporary approaches to diabetes prevention for AI/AN communities. The program supports activities that enhance or re-introduce indigenous foods and practices drawn from each grantee's landscape, history, and culture. Example activities include the cultivation of community gardens, organization of local farmers' markets, and the dissemination of culturally appropriate health messages through storytelling, audio and video recordings, and printed materials.

CDC requests OMB approval to collect standardized information, called Traditional Foods Shared Data Elements (SDE), from grantees over a three-year period. The SDE will be organized in three domains: Traditional Local Healthy Foods, Physical Activity, and Social Support for Healthy Lifestyle Change and Maintenance. Since each grantee currently maintains activity data for local program improvement, reporting summary information to CDC in SDE format is not expected to entail significant burden to respondents.

The SDE will allow CDC to compile a systematic, quantifiable inventory of activities, products, and outcomes associated with the Traditional Foods program. The SDE will also allow CDC to analyze aggregate data for improved technical assistance and overall program evaluation, reporting, and identification of outcomes; allow CDC and grantees to create a comprehensive inventory/resource library of diabetes primary prevention ideas and approaches for AI/AN communities and identify emerging best practices; and improve dissemination of success stories. The SDE will supplement the narrative progress report that grantees submit to CDC in conjunction with the annual continuation application for funding. Although these reports provide important contextual information and are useful for local program monitoring, they do not support the production of statistical reports that are needed to fully describe the Traditional Foods program and to respond to inquiries.

Respondents will be 17 Tribes and Tribal organizations that receive funding through the Traditional Foods program. The SDE will be routinely submitted to CDC semi-annually using Survey Monkey, an electronic Web-based interface. The estimated burden per response is two hours. Each grantee will receive a personalized advance notification letter, followed by an e-mail with a link to the Survey Monkey site. One of the two required SDE submissions will coincide approximately with submission of the continuation application for funding in the Spring. The second SDE submission will be scheduled annually in the Fall, at approximately the midpoint between the Spring submissions.

CDC anticipates that routine information collection will begin in April 2011 and will describe activities conducted during the period October 2010–March 2011. CDC also requests OMB approval to conduct one additional cycle of retrospective data collection during the first year of this three-year information collection request. The retrospective information collection will provide baseline SDE information about grantee activities conducted prior to October 2010, which is needed for comparison purposes and optimal overall program evaluation. Inclusion of the retrospective data will enable CDC and grantees to have a clearer, more quantifiable view of the growth of Traditional Foods activities over the five-year funding cycle for the cooperative agreement.

The total estimated burden for the one-time retrospective data collection is 34 hours (17 respondents × 2 hours/response). Annualizing this collection over three years results in an estimated annualized burden of 12 hours (6 respondents per year). The annualized figures slightly over-estimate the actual burden, due to rounding of the number of respondents for even allocation over the three-year clearance period. Second, some of the information could be collected through pre-testing the SDE collection system during Fall/Winter 2010.

There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	No. of respondents	No. of responses per respondent	Avg. burden per response (in hrs)	Total burden (in hrs)
AI/AN Tribal Grantees ...	Traditional Foods Shared Data Elements	17	2	2	68
	One-Time Retrospective Data Collection	6	1	2	12
Total	.....	.....	.....	.....	80

Dated: November 10, 2010.

Carol E. Walker,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–28930 Filed 11–16–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0532]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Nutrition Facts Label Formats

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing 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 December 17, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910—New and title "Experimental Study of Nutrition Facts Label Formats." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

I. Experimental Study of Nutrition Facts Label Format—(OMB Control No. 0910—New)

Nutrition information is required on most packaged foods and this information must be provided in a specific format as defined in 21 CFR 101.9. When FDA was determining which Nutrition Facts label format to require, the Agency undertook consumer research to evaluate alternatives (Refs. 1, 2, and 3). More recently, FDA conducted qualitative consumer research on the format of the Nutrition Facts label on behalf of the Agency's Obesity Working Group (OWG) (Ref. 4), which was formed in 2003 and tasked with outlining a plan to help confront the problem of obesity in the United States (Ref. 5). In addition to conducting consumer research, in response to the OWG plan FDA issued two advance notices of proposed rulemaking (ANPRM) requesting comments on format changes to the Nutrition Facts label. One ANPRM requested comments on whether and, if so, how to give greater emphasis to calories on the Nutrition Facts label (Ref. 6) and the other requested comments on whether and, if so, how to amend the Agency's serving size regulations (Ref. 7). In 2007, FDA issued an ANPRM requesting comments on whether the Agency should require that certain nutrients be added or removed from the Nutrition Facts label (Ref. 8).

FDA conducts consumer research under its broad statutory authority, set forth in section 903(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(2)(A), to protect the public health by ensuring that "foods are safe, wholesome, sanitary, and properly labeled;", and in section 903(d)(2)(C) (21 U.S.C. 393(d)(2)(C)), to conduct research relating to foods, drugs, cosmetics and devices in carrying out the FD&C Act.

FDA is proposing to conduct an experimental study to quantitatively assess consumer reactions to potential options for modifying the Nutrition Facts label format. The purpose of the study is to help enhance FDA's understanding of consumer comprehension and acceptance of modifications to the Nutrition Facts label format. The study is part of the Agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets.

The proposed study will use a Web-based experiment to collect information from a sample of adult members in an online consumer panel established by a contractor. The study plans to randomly assign each of 10,000 participants to view Nutrition Facts labels from a set of Nutrition Facts labels that vary by the format, the type of food product, and the quality of nutritional attributes of the product. The study will focus on the following types of consumer reactions: (1) Judgments about a food product in terms of its nutritional attributes and overall healthfulness and (2) ability to use the Nutrition Facts label to, for example, calculate calories and estimate serving sizes needed to meet objectives. To help understand consumer reactions, the study will also collect information on participants' background, including but not limited to use of the Nutrition Facts label and health status.

The study results will be used to help the Agency to understand whether modifications to the Nutrition Facts label format could help consumers make informed food choices. The results of the experimental study will not be used to develop population estimates.

In the **Federal Register** of November 18, 2009 (74 FR 59553), FDA published a 60-day notice requesting public comment on the proposed collection of information. The Agency received 36 responses, some of them containing multiple comments. The comments, and the Agency's responses, are discussed in the following paragraphs. Some of the comments received were not responsive to the comment request on the four topics of the collection of information. These non-responsive comments are not addressed.

(Comment 1) Several comments cited the importance of studying ways to improve the Nutrition Facts label on