ESTIMATE OF ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs)	Total burden (in hrs)
Total					40,894

Dated:August 25, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–22395 Filed 8–31–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–11–11KF]

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 Daniel Holcomb, CDC/ATSDR 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

Pre-Evaluation Assessments of Nutrition, Physical Activity and Obesity Programs and Policies—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The causes of obesity in the United States are complex and numerous, and they occur at social, economic, environmental, and individual levels. To address the complex nature of obesity, the Centers for Disease Control and Prevention (CDC) encourages states to adopt public health strategies that address obesity through environmental change and policies. In 2009, CDC issued guidance outlining 24 community-based strategies that can be implemented to encourage healthy eating and active living.

CDC plans to collect information about the effectiveness, in practice, of a selected group of the 24 recommended strategies. Information will be collected through a systematic process for nominating, screening and assessing promising program interventions. The study is designed to highlight local achievements and identify the most promising strategies for further development, evaluation through rigorous methods, and dissemination for widespread use. Eligible respondents include states and jurisdictions that are funded through CDC's Nutrition, Physical Activity and Obesity (NPAO) cooperative agreement program, states and jurisdictions that do not currently have NPAO funding, and other organizations.

CDC will solicit nominations for pre-evaluation assessment through on-line forums (*e.g.*, obesity prevention listservs supported by CDC and other national partners, e-mail messages, and an announcement posted on CDC's NPAO Web site). CDC will select programs for assessment by reviewing completed program nomination forms, which can be submitted on-line or in hardcopy format. The program nomination form is designed to provide information enabling an initial assessment of each candidate program's suitability for further evaluation. The topics addressed in this form include a general program description, an overview of organizational capacity, and a summary of the program's potential impact, reach to target population, feasibility, transportability, acceptability to stakeholders, and sustainability.

Up to 23 initiatives will be selected for pre-assessment evaluation over a two-year period. Selected initiatives will receive FAQs to help them understand the process, effort entailed, and public health benefit. They will also be asked to provide additional information supporting coordination of a site visit and interviews with key informants.

The primary information collection involves semi-structured, in-person interviews with approximately 12 key informants at each participating site, including: The lead administrator (1), program staff (3), evaluator (1), and community partners and other stakeholders (7). Community partners and other stakeholders will be drawn from both the private sector and the state, local, and Tribal government sector. The topics to be addressed during the site visit interviews include history and description of the initiative, stakeholder involvement, evaluation plans, and funding. Site reviewers will also collect contextual information about program implementation through direct observation, which does not entail burden to respondents.

Results will be used to identify promising practices in nutrition, physical activity, and obesity used by NPAO grantees and others in the obesity prevention field; provide feedback and technical assistance to each initiative's developers, implementers and managers; and assess the evaluation readiness of obesity prevention initiatives, thereby encouraging the judicious use of scarce evaluation resources.

OMB approval will be requested for two years. Authority to collect information is provided to CDC under Sections 301 (a) and 317 (k) of the Public Health Service Act. CDC anticipates reviewing approximately 51 program nomination forms per year. Site visits will be conducted with an average of 12 programs per year.

Participation is voluntary. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs)	Total burden (in hrs)
Nominator	Nomination Form	51	1	1	51
Lead Administrator	Site Visit Availability Calendar	12	1	1	12
	Suggested Interviewees Form	12	1	1	12
	Site Visit Schedule Instructions and Template.	12	1	5	60
	Interview Guide for Lead Administrator	12	1	2	24
Evaluator	Interview Guide for Evaluator	12	1	1	12
Program Staff	Interview Guide for Program Staff	36	1	1	36
State, Local and Tribal Govt. Sector Partners.	Interview Guide for Community Partners and Other Stakeholders.	48	1	1	48
Private Sector Partners	Interview Guide for Community Partners and Other Stakeholders.	36	1	1	36
Total					291

Date: August 26, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–22384 Filed 8–31–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–1542 (formerly Docket No. 00D–0892)]

Guidance on Positron Emission Tomography Drug Applications—Content and Format for New Drug Applications and Abbreviated New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''PET Drug Applications—Content and Format for NDAs and ANDAs.'' This document is intended to assist manufacturers of certain positron emission tomography (PET) drugs in submitting new drug applications (NDAs) or abbreviated new drug applications (ANDAs) in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA regulations.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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: Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6164, Silver Spring, MD 20993, 301–796–3416.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''PET Drug Applications—Content and Format for NDAs and ANDAs.'' The guidance is intended to assist the manufacturers of certain PET drugs—fludeoxyglucose F 18 injection, ammonia N 13 injection, and sodium fluoride F 18 injection—in submitting NDAs and ANDAs in accordance with the FD&C Act and FDA regulations. The guidance states that to continue marketing these PET drugs for clinical use, manufacturers of these drugs must submit NDAs of the type described in section 505(b)(2) of the FD&C Act (21 U.S.C. 355(b)(2)) or ANDAs under section 505(j) of the FD&C Act by December 12, 2011. The guidance further explains when submission of a 505(b)(2) application or ANDA is appropriate and describes the information that manufacturers of these PET drugs include in each type of application.

A revised draft guidance of the same title was announced in the **Federal Register** on February 3, 2011 (76 FR 6143), and Docket No. FDA–2000–D–1542 was open for comments until April 4, 2011. The February 3, 2011, draft guidance was a revision of the document ''Draft Guidance for Industry on the Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products,'' issued on March 10, 2000 (65 FR 13010). The February 3, 2011, revised guidance was issued as a draft for comment because FDA's perspective has changed significantly since the issuance of the March 2000 draft guidance. We received comments from industry and professional societies. We have carefully considered and, where appropriate, we have made corrections, added information, or clarified the information in this guidance in response to the comments or on our own initiative.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the submission of NDAs and ANDAs for PET drugs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the