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]

BILLING CODE 4163–18–P

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

heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information required on Form FDA–356h have been approved under OMB control number 0910–0338; and the collections of information required on Form FDA–3397 have been approved under OMB control number 0910–0297.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: August 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–22373 Filed 8–31–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request New proposed collection, Biospecimen and Physical Measures Formative Research Methodology Studies for the National Children's Study

SUMMARY: Under the provisions of Section (3507(a)(1)(D)) of the Paperwork Reduction Act of 1995, the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 27, 2011, pages 23609–23611, and allowed 60 days for public comment. Two written comments and two verbal comments were received. The verbal comments expressed support for the broad scope of the study. The written comments were identical and questioned the cost and utility of the study. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Biospecimen and Physical Measures Formative Research Methodology Studies for the National Children's Study (NCS). *Type of Information Request: NEW. Need and Use of Information Collection:* The Children's Health Act of 2000 (Pub. L. 106–310) states:

(a) PURPOSE.—It is the purpose of this section to authorize the National Institute of Child Health and Human Development* to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

(b) IN GENERAL.—The Director of the National Institute of Child Health and Human Development* shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—

(1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

(2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.

(c) REQUIREMENT.—The study under subsection (b) shall—

(1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;

(2) gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and

(3) consider health disparities among children, which may include the consideration of prenatal exposures.

To fulfill the requirements of the Children's Health Act, the results of formative research tests will be used to maximize the efficiency (measured by scientific robustness, participant and infrastructure burden, and cost) of biospecimen and physical measurement collection procedures, accompanying questionnaires, storage and information management processes, and assay procedures, thereby informing data collection methodologies for the National Children's Study (NCS) Vanguard and Main Studies. With this submission, the NCS seeks to obtain OMB's generic clearance to conduct formative research featuring biospecimen and physical measurement collections.

The results from these formative research projects will inform the feasibility (scientific robustness), acceptability (burden to participants and study logistics) and cost of NCS Vanguard and Main Study biospecimen collection procedures and physical measurements in a manner that minimizes public information collection burden compared to burden anticipated if these projects were incorporated directly into either the NCS Vanguard or Main Study. *Frequency of Response:* Annual [As needed on an on-going and concurrent basis]. *Affected Public:* Members of the public, researchers, practitioners, and other health professionals. *Type of Respondents:* Women of child-bearing age, infants, children, fathers, health care facilities and professionals, public health professional organizations and practitioners, and hospital administrators. These include both persons enrolled in the NCS Vanguard Study and their peers who are not participating in the NCS Vanguard Study. *Annual reporting burden:* See Table 1. The annualized cost to respondents is estimated at: $600,000 (based on $10 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN SUMMARY, BIOLOGICAL AND PHYSICAL MEASURES

Data collection activity	Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Blood:					
Adult	NCS participants	4,000	1	0.5	2,000