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—fluodeoxyglucose 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A revised draft guidance of the same title was announced in the Federal Register on February 3, 2011 (76 FR 6143), and Docket No. FDA–2000–D–1542 was open for comments until April 4,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 The February 3, 2011, draft guidance was a revision of the document “Draft Guidance for Industry on the Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products,”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issued as a draft for comment because FDA’s perspective has changed significantly since the issuance of the March 2000 draft guidance.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.

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—fluodeoxyglucose 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.

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
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.


(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 children’s health and human development; and

(2) identify 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           |


*Referred to as the National Institute of Child Health and Human Development (NICHD).