MD 20993–002, 301–796–5333, email: *ronald.fitzmartin@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On December 17, 2014, FDA published a final guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' (eStudy Data) posted on FDA's Study Data Standards Resources Web page at *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm*. The eStudy Data guidance implements the electronic submission requirements of section 745A(a) of the FD&C Act (21 U.S.C. 379k–1) for study data contained in new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and investigational new drug applications (INDs) to CBER or CDER by specifying the format for electronic submissions. The initial timetable for the implementation of electronic submission requirements for study data is December 17, 2016 (24 months after issuance of final guidance for NDAs, BLAs, ANDAs, and 36 months for INDs). The eStudy Data guidance states that a **Federal Register** notice will specify the transition date for all version updates (with the month and day for the transition date corresponding to March 15).

The transition date for support (see section II. Exceptions) of the 3.2 version of CDISC STDM IG is March 15, 2017. Although SDTM IG version 3.2 is supported as of this **Federal Register** notice and sponsors or applicants are encouraged to begin using it, the new version will only be required in submissions for studies that start after March 15, 2018. The Catalog will list March 15, 2018, as the ''date requirement begins.'' When multiple versions of an FDA-supported standard are listed in the Catalog, sponsors or applicants can select a version to use.

II. Exceptions

The following SDTM IG 3.2 domains have not completed testing and acceptance and are not supported at this time: Death Details and Exposure as Collected. The therapeutic area (TA) standards (*http://www.cdisc.org/*) that are included in SDTM IG 3.2 have not completed testing and acceptance and are not supported at this time. The specific domain and the TA standard are listed in the table that follows:

SDTM IG 3.2 Domain	TA User guide
1. Healthcare Encounters	Cardiovascular Studies, 1.0; Polycystic Kidney Disease, 1.0; Asthma, 1.0.
2. Microscopic Findings	Tuberculosis, 1.0; Parkinson's, 1.0.
3. Morphology	Cardiovascular Studies, 1.0; Parkinson's, 1.0; Polycystic Kidney Disease, 1.0; Alzheimer's, 1.0; Multiple Sclerosis, 1.0.
4. Procedures	Cardiovascular Studies, 1.0; Polycystic Kidney Disease, 1.0; Alzheimer's, 1.0.
5. Reproductive System	Polycystic Kidney Disease, 1.0.
6. Disease Response	Tuberculosis, 1.0.
7. Skin Response	Asthma, 1.0.

Sponsors and applicants with questions on how to implement the FDA-supported study data standards should contact and work with FDA technical staff. For questions, contact CDER at *cder-edata@fda.hhs.gov* or CBER at *cber.cdisc@fda.hhs.gov*.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the proposed recommendations at either *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm* or *http://www.regulations.gov*.

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20316 Filed 8–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–New–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit a new Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before October 19, 2015.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS–OS–0990–New–60D.

Information Collection Request Title: Evaluation of the Office on Women's Health Coalition for a Healthier Community Initiative

Abstract: This collection is to provide data for the national evaluation of the U.S. Department of Health and Human Services (HHS), Office on Women's Health (OWH) Coalition for a Healthier Community (CHC) Initiative. The initiative supports 10 communities with grants to support coalitions in implementing gender-based public health systems approaches, evidence-based health interventions, and outreach and education activities to reduce barriers to and enhance facilitators of improvements in women and girls' health. Each of the grantees has implemented an IRB-approved local evaluation; however, OWH is seeking to

collect core data across grantees to examine the extent to which the Government's investment has resulted in achieving OWH-related *Healthy People 2020* priorities and yields lessons learned upon which to plan future initiatives related to its mission.

Likely Respondents: The proposed collection includes plans for interviews with key staff (project directors, project coordinators, local evaluators), coalition members (including chairs and co-chairs), and community leaders connected to the coalitions. These respondents will also complete online surveys about their perceptions of the changes in their community as a result of coalition activities. Program participants and other community members exposed to the coalitions' activities through social media will also complete online surveys. Project directors and local evaluators also annually provide information to OWH on their coalition's functioning, the status of the cost-effectiveness analysis for their coalition's interventions, and the coalition's plans for sustainability. The following table summarizes the ''Total Estimated Annualized Burden—Hours'' by form and type of respondent.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden hours
1—Key Persons Discussion Guide for Telephone Interviews	90	2	1	180
2—Key Persons, Coalition Members, and Community Leaders Online Survey	200	1	20/60	67
3—Coalition Participants and Other Community Members Online Survey	510	1	20/60	170
4—Grantee Annual Report on Coalition Functioning, Cost-Effectiveness, and Sustainability Planning	10	2	2	40
Total				457

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Terry S. Clark,

Assistant Information Collection Clearance Officer.

[FR Doc. 2015–20357 Filed 8–17–15; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the AIDS Research Advisory Committee, NIAID.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: AIDS Research Advisory Committee, NIAID AIDS Vaccine Research Subcommittee, NIAID.

Date: September 22, 2015.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: Presentations by invited speakers to discuss correlates of AIDS vaccine protection studies in nonhuman primates. In addition, there will be presentations and discussion on vaccine-specific HLA–E and class II-restricted CD8+ cells and their role in nonhuman primate protection observed with AIDS vaccines based on CMV vectors.

Place: National Institutes of Health, Conference Room 1D13, 5601 Fishers Lane, Rockville, MD 20892.

Contact Person: James A. Bradac, Ph.D., Executive Secretary, AVRS, Division of AIDS, Room 9B60, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9829, Rockville, MD 20892–9829, 301–435–3754, *jbradac@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 13, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–20330 Filed 8–17–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board.

Date: September 16, 2015.

Open: 1:00 p.m. to 2:00 p.m.

Agenda: Director's report and business of the Board.

Closed: 2:00 p.m. to 3:00 p.m.