

discuss the disease, its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of available therapies. These meetings include participation of FDA review divisions, the relevant patient community, and other interested stakeholders.

II. Disease Area Selection

On October 8, 2014, FDA published a **Federal Register** notice (79 FR 60857) that requested public comment on potential disease areas to be addressed in FYs 2016–2017. In that notice, based on several criteria listed, FDA identified 16 disease areas as potential candidates for remaining public meetings and invited public comment on the preliminary list and on disease areas that were not listed.

Following publication of the notice, almost 2,700 comments addressing over 50 disease areas were submitted by patients, patient advocates and advocacy groups, caregivers, healthcare providers, professional societies, scientific and academic experts, pharmaceutical companies, and others. The majority of comments received were submitted by individual patients. The comments focused generally on nominating individual disease areas or groups of disease areas to be addressed and on providing general suggestions for the Patient-Focused Drug Development Initiative. The comments received also discussed the impact of these nominated diseases on the patients' daily lives, the symptoms that were most concerning to patients, and the nature of (or lack of) specific treatments for these diseases. The majority of comments received concerned lewy body dementia, frontotemporal lobar degeneration, and neuropathies. Other disease areas, such as hereditary angioedema, dystonia, temporomandibular disorders, lupus, alopecia areata, chronic lymphocytic leukemia, trigeminal neuralgia, and arachnoiditis, also received a significant number of comments.

In selecting the disease areas of focus for the Patient-Focused Drug Development Initiative of FYs 2016–2017, FDA carefully considered the valuable public comments received, the perspectives of reviewing divisions at FDA, and the following selection criteria, which were published in the October 8, 2014, **Federal Register** notice:

- Disease areas that are chronic, symptomatic, or affect functioning and activities of daily living;

- Disease areas for which aspects of the disease are not formally captured in clinical trials;

- Disease areas for which there are currently no therapies or very few therapies, or the available therapies do not directly affect how a patient feels, functions, or survives; and

- Disease areas that have a severe impact on identifiable subpopulations (such as children or the elderly).

FDA's selection also reflects disease areas from FDA review divisions that were not covered by the meetings held during FYs 2013–15. For its FYs 2016–2017 list of disease areas, FDA has added a broad range of diseases based upon disease severity (less severe to more severe) and upon the size of the affected population (rare diseases to more prevalent diseases). FDA has identified the following diseases to be the focus of meetings scheduled in FYs 2016–2017:

- Alopecia areata
- Autism
- Hereditary angioedema
- Non-tuberculous mycobacterial infections
- Patients who have received an organ transplant
- Psoriasis
- Neuropathic pain associated with peripheral neuropathy
- Sarcopenia

A schedule of the meetings planned can be found at the FDA Patient-Focused Drug Development Web site, which is described in section III of this notice. The Agency recognizes that there are many more disease areas than can be addressed in the planned FDA meetings under the formal PDUFA V commitment, and FDA will seek other opportunities to gather public input on disease areas not addressed through this Patient-Focused Drug Development Initiative. FDA encourages stakeholders to identify and organize patient-focused collaborations to generate public input on other disease areas using the process established through this Patient-Focused Drug Development Initiative as a model. Information on additional opportunities for gathering patient input can be found on the Patient-Focused Drug Development Web site.

III. Patient-Focused Drug Development Web Site

FDA's Web site on Patient-Focused Drug Development is available online at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm>. This Web site contains the general schedule of upcoming meetings for FYs 2016–2017, information on how stakeholders can

prepare for these upcoming meetings, and information on how stakeholders may leverage the Patient-Focused Drug Development Initiative to generate input on disease areas not addressed through the Patient-Focused Drug Development PDUFA V commitment. The Web site will be updated as new information becomes available.

Dated: June 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16359 Filed 7–1–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: HHS–OS–0937–0166–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of Population Affairs, Office of the Assistant Secretary for Health, 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 an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0937–0166, which expires on October 31, 2015. 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 August 31, 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–0937–0166–60D for reference.

Information Collection Request Title: HHS 42 CFR part 50, subpart B; Sterilization of Persons in Federally Assisted Family Planning Projects—OMB No. 0937–0166—Extension—OASH, Office of Population Affairs—Office of Family Planning

Abstract: This is a request for extension of a currently approved collection for the disclosure and record-keeping requirements codified at 42 CFR part 50, subpart B (“Sterilization of Persons in Federally Assisted Family Planning Projects”). The consent form solicits information to assure voluntary and informed consent to persons undergoing sterilization in programs of health services which are supported by federal financial assistance administered by the Public Health Service (PHS). Consent forms are signed

by individuals undergoing a federally funded sterilization procedure and certified by necessary medical authorities. Forms are incorporated into the patient’s medical records and the agency’s records. Through periodic site audits and visits, PHS staff review completed consent forms to determine compliance with the regulation. Thus, the purpose of the consent form is twofold. First, it serves as a mechanism to ensure that a person receives information about sterilization and voluntarily consents to the procedure.

Second, it facilitates compliance monitoring. The Sterilization Consent Form has been revised to reflect a new expiration date on the Required Consent Form. There are no other revisions to the form.

Likely Respondents: Interested persons who desire to send comments regarding this burden estimate or any other aspect of this collection of information that OS specifically requests comments.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Type of respondent	Information collection	Number of respondents	Number of responses per respondent	Average burden per response	Total hours
Citizens Seeking Sterilization	Information Disclosure for <i>Sterilization Consent Form.</i>	100,000	1	1	100,000
Citizens Seeking Sterilization	Record-keeping for <i>Sterilization Consent Form.</i>	100,000	1	15/60	25,000
Total	125,000

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,
Asst Information Collection Clearance Officer.

[FR Doc. 2015–16256 Filed 7–1–15; 8:45 am]

BILLING CODE 4150–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Notice of Closed Meeting

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

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 Institute Special Emphasis Panel, NCI Program Project Meeting 1 (P01).

Date: October 8–9, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Caterina Bianco, MD, Ph.D., Scientific Review Officer, Research Program Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W610, Bethesda, MD 20892–9750, 240–276–6459, biancoc@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: June 26, 2015.

Melanie J. Gray,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–16213 Filed 7–1–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Cardiovascular Sciences.

Date: July 20, 2015.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 4136, Bethesda, MD 20892, 301–435–0904, sara.ahlgren@nih.gov.