• Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.

• Inspection, via metal detector or other applicable means, of all persons entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

**Note:** Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

**Authority:** Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102–3).

Dated: February 18, 2016.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2016–04091 Filed 2–24–16; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–N–0001]**

### Developing an Evidentiary Standards Framework for Safety Biomarkers Qualification; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA), in co-sponsorship with the Foundation for the National Institutes of Health Biomarkers Consortium (FNIH BC), is announcing a public workshop entitled ''Developing an Evidentiary Standards Framework for Safety Biomarkers Qualification Workshop.'' The purpose of the workshop is to discuss the evidentiary standards needed to support biomarker qualification with a particular emphasis on drug safety markers. The 2-day workshop will focus on the standards relevant to the qualification of a range of safety biomarkers and examine case studies in several different organ systems.

**DATES:** The public workshop will be held on April 14, 2016, from 9 a.m. to 5 p.m. and April 15, 2016, from 8 a.m. to 5 p.m.

**ADDRESSES:** The public workshop will be held at the Bethesda North Marriott Hotel and Conference Center, 5701 Marinelli Rd., Bethesda, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Janelle Lewis, Foundation for the National Institutes of Health, 9650 Rockville Pike, Bethesda, MD 20814, 301–594–2919, FAX: 301–480–2752, email: *jlewis@fnih.org.*

**SUPPLEMENTARY INFORMATION:** The need for evidentiary standards to qualify biomarkers was identified in FDA's Critical Path Initiative as essential to improving the efficiency and effectiveness of drug development. Evidentiary standards vary among different types of biomarkers and according to the context(s) of use (COU) for which qualification is being considered, and there are specific challenges involved in qualifying drug safety biomarkers. This workshop is aimed at creating alignment among scientific stakeholders including FDA, the National Institutes of Health (NIH), the biopharmaceutical industry, academic researchers, and patient groups regarding a proposed framework for determining the levels of evidence required to qualify biomarkers for use in drug development, with an emphasis on biomarkers used in determinations of drug safety assessments. Development of a general framework for biomarker qualification will be discussed, along with specific application to different COUs related to drug safety, including consideration of several specific case studies involving qualification of clinical markers of toxicity in different organ systems.

*Registration:* There is no fee to attend the workshop, but attendees must register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at *www.fnih.org/evidentiarystandardsworkshop* by April 1, 2016. For those persons without Internet access, please contact Janelle Lewis at the Foundation for the NIH (see **FOR FURTHER INFORMATION CONTACT**) to register.

Attendees are responsible for their own hotel accommodations. Attendees making reservations at the Bethesda North Marriott Hotel and Conference Center (see **ADDRESSES**) are eligible for a reduced rate of $226 per night (equivalent to the government per diem rate), not including applicable taxes. To receive the reduced rate, follow the Web link that will be provided to you upon completion of online registration.

If you need special accommodations due to a disability, please contact Janelle Lewis (see **FOR FURTHER INFORMATION CONTACT**) at the Foundation for the NIH at least 7 days in advance of the workshop.

Dated: February 19, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–04027 Filed 2–24–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

**[Document Identifier: OS–4040–0010 60D]**

### Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

**AGENCY:** Electronic Government Office, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Electronic Government Office (EGOV), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a 3-year extension for OMB Control Number 4040–0010. The ICR will expire on September 30, 2016. The 4040–0010 is composed of the following forms: Project Abstract; Project Performance Site Location(s); and Key Contacts. The ICR also requests categorizing these forms as common forms, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

**DATES:** Comments on the ICR must be received on or before April 25, 2016.

**ADDRESSES:** Submit your comments to *ed.calimag@hhs.gov* or (202) 690–7569.

**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 OMB control number 4040–0010. Form is available at *http://www.grants.gov* or upon request.

*Information Collection Request Title:* Project Abstract; Project Performance Site Location(s); Key Contacts.

*OMB No.:* 4040–0010.

*Abstract:* The Project Abstract; Project Performance Site Location(s); Key Contacts forms are used by Federal grant-making agencies for applicants to apply for Federal financial assistance.

*Need and Proposed Use of the Information:* The Project Abstract; Project Performance Site Location(s); Key Contacts forms are used by the public to apply for Federal financial assistance in the form of grants. These forms are submitted to the Federal grant-making agencies for evaluation and review.

*Likely Respondents:* Organizations and institutions seeking grants.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

HHS estimates that each of the respective forms will take 1 hour to complete. Once OMB approves the use of the Project Abstract; Project Performance Site Location(s); Key Contacts forms as common forms, federal agencies may request OMB approval to use this common form without having to publish notices and request public comments for 60 and 30 days. Each agency must account for the burden associated with their use of the common form.

EGOV 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.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

| Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|
| Project Abstract | 85 | 1 | 1 | 85 |
| Project Performance Site Location(s) | 143,567 | 1 | 1 | 143,567 |
| Key Contacts | 3,565 | 1 | 1 | 3,565 |
| Total | 147,217 | | | 147,217 |

**Darius Taylor,**

*Information Collection Clearance Officer.*

[FR Doc. 2016–04056 Filed 2–24–16; 8:45 am]

**BILLING CODE 4150–57–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

**[Document Identifier: OS–4040–0001 60D]**

### Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

**AGENCY:** Electronic Government Office, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Electronic Government Office (EGOV), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a 3-year extension for OMB Control Number 4040–0001. The ICR will expire on June 30, 2016. The ICR also requests categorizing 4040–0001 as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

**DATES:** Comments on the ICR must be received on or before April 25, 2016.

**ADDRESSES:** Submit your comments to *ed.calimag@hhs.gov* or (202) 690–7569.

**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 OMB control number 4040–0001. Form is available *http://www.grants.gov* or upon request.

*Information Collection Request Title:* SF–424 Application for Federal Assistance—Research and Related.

*OMB No.:* 4040–0001.

*Abstract:* The SF–424 Application for Federal Assistance—Research and Related is a set of common forms used by Federal research grant-making agencies for organizations to apply for Federal financial assistance.

*Need and Proposed Use of the Information:* The SF–424 Application for Federal Assistance—Research and Related forms are used by organizations to apply for Federal financial assistance in the form of research-based grants. These forms are submitted to the Federal grant-making agencies for evaluation and review.

*Likely Respondents:* Organizations and institutions seeking research-based grants. Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying