functions. The Agencies seek input on these three categories of health IT.

A. Promote the Use of Quality Management Principles

The Agencies seek input on the following questions related to promoting the use of quality management principles in health IT:

1. What essential quality management principles should apply to health IT? How should they apply to different stakeholders and at different stages of the health IT product lifecycle?

2. How do we assure stakeholder accountability for adoption of quality management principles? Is there a role for a non-governmental, independent program to assess stakeholder adherence to quality management principles? Is there a role for government?

B. Identify, Develop, and Adopt Standards and Best Practices

The Agencies seek input on the following questions related to identification, development, and adoption of standards and best practices in health IT:

1. Are the identified priority areas for standards and best practices the proper areas of focus? If not, what areas should be prioritized?

2. How can the private sector help facilitate the development and adoption of applicable health IT standards and best practices? Is there a role for a non-governmental, independent program to assess product and stakeholder adherence to standards and best practices? Is there a role for government?

C. Leverage Conformity Assessment Tools

The Agencies seek input on the following questions related to clarifying the value and role of conformity assessment tools in health IT:

1. What conformity assessment tools, if any, should be incorporated into a risk-based health IT framework? How should they apply to different stakeholders and at different stages of the health IT product lifecycle? How can adoption of and adherence to conformity assessment programs be promoted?

2. Should interoperability be tested? How should tests to validate interoperability be conducted? Should interoperability standard(s) be adopted and used for conformity assessments (i.e. develop a functional standard that specifies interoperability characteristics that could be used for conformity assessment)?

3. How should the intended user (e.g. health care provider, consumer, etc.) affect the type of conformity assessment performed?

4. How should conformance assessment results be communicated to stakeholders?

5. Is there a role for a non-governmental, independent health IT conformity assessment program? Is there a role for government? Should the ONC Health IT Certification Program be leveraged to protect patient safety through the use of conformity assessment tools?

D. Create an Environment of Learning and Continual Improvement

The Agencies seek public input on the following questions related to creating an environment of learning and continual improvement:

1. What should be the governance structure and functions of the Health IT Safety Center, in order for it to serve as a central point for a learning environment, complement existing systems, facilitate reporting, and promote transparent sharing of adverse events, near misses, lessons learned, and best practices?

2. How can comparative user experiences with health IT be captured and made available to the health IT community and other members of the public to promote learning?

3. How can the private sector help facilitate the development of a non-governmental process for listing selected health IT products? What types of products and information should be included? Should the results of conformity assessments, such as conformance with certain clinical or privacy and security standards, be included?

4. In terms of risk management, what type of safety-related surveillance is appropriate for health IT products categorized as health management functionality? What continued or expanded role(s), if any, should the ONC Health IT Certification Program play in the safety-related surveillance of health IT products?

5. What role should government play in creating an environment of learning and continual improvement for health IT?

E. Clinical Decision Support

The Agencies seek public input on the following questions related to clinical decision support (CDS):

1. What types of CDS functionality should be subject to the health management health IT framework? Which types should be the focus of FDA oversight?

2. How should the following priority areas identified in the health management health IT framework be applied to CDS categorized as health management health IT functionality?

a. *Quality management principles.*

b. *Standards and best practices.*

c. *Conformity assessments.*

d. *Learning environment and continual improvement.*

3. Are there additional safeguards for CDS, such as greater transparency with respect to CDS rules and information sources that are needed to appropriately balance patient safety and the promotion of innovation?

4. Does the certification of CDS functionalities, such as those functionalities currently certified under the ONC Health IT Certification Program, sufficiently balance patient safety and the promotion of innovation?

5. How can the private sector help assure the facilitation of the development, application and adoption of high quality CDS with health management health IT functionality in lieu of a regulatory approach? What role, if any, should government play?

Dated: April 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08653 Filed 4–15–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1658]

Characterizing and Communicating Uncertainty in the Assessment of Benefits and Risks in Drug Regulatory Decision-Making; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; rescheduling of public workshop; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rescheduling of a February 13, 2014, public workshop convened by the Institute of Medicine (IOM) entitled ''Characterizing and Communicating Uncertainty in the Assessment of Benefits and Risks in Drug Regulatory Decision-Making,'' published in the **Federal Register** of January 10, 2014. Due to inclement weather, the Federal Government was closed on February 13, 2014. We are rescheduling the public workshop to May 12, 2014, and extending the comment period for the public docket.

DATES: The public workshop will be held on May 12, 2014, from 9 a.m. to approximately 5 p.m. Registration to attend the workshop must be received by May 7, 2014. See the **SUPPLEMENTARY INFORMATION** section for information on how to register for the workshop. Submit either electronic or written comments by June 11, 2014.

ADDRESSES: The workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Sections B and C of the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit electronic comments 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sara Eggers, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave. Bldg. 51, Rm. 1166, Silver Spring, MD 20993–0002, 301–796–4904, FAX: 301–847–8443, email: *sara.eggers@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 10, 2014 (79 FR 1877), FDA announced a 2-day public workshop on February 12–13, 2014. Due to the Federal Government closure on February 13, 2014, the workshop was postponed. We are rescheduling the public workshop to May 12, 2014, and extending the comment period to June 11, 2014 (see **DATES**). The purpose of the workshop is twofold: (1) To explore potential approaches to addressing and communicating uncertainty and (2) to identify key considerations on developing, evaluating, and incorporating potential approaches to addressing uncertainty into the assessment of benefits and risks in the human drug review process. Additional information about the purpose of the workshop, topics for discussion, and registration is available on FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm378861.htm,* and is provided in the January 10, 2014, **Federal Register** notice, which is also available on FDA's Web site.

Dated: April 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08591 Filed 4–15–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Cancellation of Meeting

Notice is hereby given of the cancellation of the Center for Scientific Review Special Emphasis Panel, April 14, 2014, 10:00 a.m. to April 14, 2014, 8:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on April 7, 2014, 79 FR 19103.

The meeting is cancelled due to the reassignment of applications.

Dated: April 10, 2014.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–08557 Filed 4–15–14; 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 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: Center for Scientific Review Special Emphasis Panel Myalgic Encephalomyelitis/Chronic Fatigue Syndrome

Date: April 30, 2014.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Lynn E Luethke, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5166, MSC 7844, Bethesda, MD 20892, (301) 806–3323, *luethkel@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS).

Dated: April 10, 2014.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–08560 Filed 4–15–14; 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 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: Center for Scientific Review Special Emphasis Panel Member Conflict: Immune Mechanism.

Date: April 14, 2014.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Scott Jakes, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7812, Bethesda, MD 20892, 301–495–1506, *jakesse@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844,