

registrations and listings for additional information is estimated to be 12,375 hours, and the annual respondent recordkeeping burden is estimated to be 45,000 hours. Therefore, the total burden hours for this collection are estimated to be 57,375. The estimates

cited in tables 1 and 2 of this document are based primarily on fiscal year 2010 data from current systems and on conversations with industry and trade association representatives.

In the **Federal Register** of December 7, 2010 (75 FR 76008), FDA published a

60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

| 21 CFR section     | No. of respondents | No. of responses per respondent | Total annual respondents | Average burden per response (in hours) | Total hours |
|--------------------|--------------------|---------------------------------|--------------------------|--|-------------|
| 807.31(d)(2) ..... | 2,250              | 1                               | 2,250                    | 0.5                                    | 1,125       |
| 807.31(e) .....    | 22,500             | 1                               | 22,500                   | 0.5                                    | 11,250      |
| Total .....        |                    |                                 |                          |  | 12,375      |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

| 21 CFR section         | No. of record-keepers | No. of records per record-keeper | Total annual records | Average burden per recordkeeping (in hours) | Total hours |
|------------------------|-----------------------|----------------------------------|----------------------|---|-------------|
| 807.31(a) to (c) ..... | 22,500                | 4                                | 90,000               | 0.5   | 45,000      |
| Total .....            |                       |                                  |                      |   | 45,000      |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 24, 2011.

**Leslie Kux,**  
Acting Assistant Commissioner for Policy.

[FR Doc. 2011-7389 Filed 3-29-11; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0002]

**Medical Device Epidemiology Network 2011: Second Annual Public Workshop**

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

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled “Medical Device Epidemiology Network (MDEpiNet) 2011: Second Annual Public Workshop.” The purpose of the public workshop is to provide a public update on the development of MDEpiNet and to facilitate discussion among FDA and all stakeholders with expertise in epidemiology and health services research on issues related to the methodology for studying medical device performance.

**DATE AND TIME:** The public workshop will be held on April 25, 2011 from 8 a.m. to 5 p.m. Participants are

encouraged to arrive early to ensure time for parking and security screening before the meeting. Registration will begin at 7 a.m.

**LOCATION:** The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (the Great Room), Silver Spring, MD 20993.

**CONTACTS:** Mary Beth Ritchey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 301-796-6638, *e-mail:* [MaryElizabeth.Ritchey@fda.hhs.gov](mailto:MaryElizabeth.Ritchey@fda.hhs.gov); or Ellen Pinnow, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6066, *e-mail:* [Ellen.Pinnow@fda.hhs.gov](mailto:Ellen.Pinnow@fda.hhs.gov).

**Registration:** Registration is available through April 15, 2011, at the following Web site: <http://fda-ws.s-3.net/EpiNetWSApr11/>. There is no fee to attend the workshop, but attendees must register in advance. Registration will be on a first-come, first-served basis and we ask that one person per institution be selected to represent the entity at the workshop. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. If you need special accommodations because of a disability, please contact

Mary Beth Ritchey (*see CONTACTS*) at least 7 days before the public workshop.

**SUPPLEMENTARY INFORMATION:**

**I. Why are we holding this public workshop?**

The purpose of the public workshop is to facilitate continuing discussion among FDA, the academic epidemiology and health services research community, and all stakeholders on issues related to the methodology of studies for medical device performance. We aim to describe and solicit feedback on the establishment of a network that works with FDA experts to determine the evidence gaps and questions, datasets and approaches for conducting robust analytic studies and improve our understanding of the performance of medical devices (including comparative effectiveness studies). We also aim to reach out to stakeholders to initiate development of scientific, methodology, and device-area priorities for MDEpiNet.

**II. Who is the target audience for this public workshop? Who should attend this public workshop?**

This workshop is open to all interested parties. The target audience is comprised of academic researchers with experience in epidemiology or health services research with an interest in medical device outcome and epidemiologic study methodology.

### III. What are the topics we intend to address at the public workshop?

We intend to discuss a large number of issues at the workshop, including, but not limited to the following:

- Establishment of the MDEpiNet infrastructure,
- Gaps and challenges in medical device outcomes and epidemiologic studies,
- Opportunities for medical device epidemiologic research and partnerships between the Center for Devices and Radiological Health and academia.

### IV. Where can I find out more about this public workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at <http://fda-ws.s-3.net/EpiNetWSApr11/>.

Dated: March 25, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-7434 Filed 3-29-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Forum for State and Territorial Chief Executives (National Forum) Program Cooperative Agreement

**AGENCY:** Health Resources and Services Administration (HRSA), HHS.

**ACTION:** Notice of Non-competitive One-Year Extension With Funds for the National Forum for State and Territorial Chief Executives (National Forum) Program Cooperative Agreement.

**SUMMARY:** HRSA will be providing a one-year extension with funds in the amount authorized in fiscal year (FY) 2010 to support activities that focus on cross-cutting publicly-funded health program integration and health access issues identified by the State and Territory governors and their senior health policy advisors, including addressing the needs of uninsured, underinsured and special needs populations, oral health, border health and health information technology as well as HRSA's overall strategic goals.

**SUPPLEMENTARY INFORMATION:**

*Cooperative Agreement Recipient of Record:* National Governors Association Center for Best Practices (NGA), Washington, DC.

*Original Period of Support:* April 1, 2008, to March 31, 2011.

*Amount of Supplement Award:* \$160,000.

*Authority:* Sections 241 and 301 of the Public Health Service Act, as amended (42 U.S.C. 238J and 241 respectively).

*CFDA Number:* 93.224.

*Justification for the Exception to Competition:* The National Forum cooperative agreement provides a unique vehicle for HRSA to collaborate with the Nation's governors on their shared priorities, and provides opportunities through which governors can build on lessons others states have learned in addressing similar health policy challenges. A 1-year extension with funds will allow the National Forum to facilitate ongoing communication on emerging strategies addressing common priorities, public health policy, and governance issues affecting States and Territories thereby allowing HRSA to reevaluate the focus and implementation of this Program prior to the FY 2012 competition for the next 3-year project period. Further funding beyond March 31, 2012, will be competitively awarded in FY 2012.

**FOR FURTHER INFORMATION CONTACT:**

Mark Pincus, Director, Office of Policy Analysis, HRSA, via *e-mail*: [mpincus@hrsa.gov](mailto:mpincus@hrsa.gov) or via *telephone*: 301-443-5911.

Dated: March 23, 2011.

**Mary K. Wakefield,**

*Administrator.*

[FR Doc. 2011-7444 Filed 3-29-11; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; 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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK Central Repositories Non-Renewable Sample Access (X01)-Hepatitis C.

*Date:* April 26, 2011.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call)

*Contact Person:* Najma Begum, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, [begumn@nidddk.nih.gov](mailto:begumn@nidddk.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 24, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-7500 Filed 3-29-11; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; 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:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; "Mouse Resource".

*Date:* April 20, 2011.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call)

*Contact Person:* Gregory P. Jarosik, PhD, Scientific Review Administrator, Scientific