products. Such systems have been put in place for drugs that are or are suspected to be teratogenic, and the programs are designed to ensure patients are not pregnant and will not become pregnant while taking the drug. Such systems create burdens on patients and the health care system. Is such a system necessary for opioids? How would such a program be implemented given the number of patients, prescribers, and other health care providers involved in their use?

2. Should the REMS include controls on distributors who distribute products to pharmacies and other health care providers? What controls are necessary, and how can they be efficiently provided without being unduly burdensome on the health care system?

3. What existing systems (for example, in pharmacies) already exist that could be used to implement a REMS? For example, could patient information be provided through existing pharmacy systems to patients? Are there systems for providing education to prescribers that could be used to provide the educational component of a REMS?

4. FDAAA requires that innovator and generic application holders use a single, shared system to provide a REMS with elements to assure safe use. What obstacles need to be addressed before such a system could be developed?

5. What metrics should be used to assess the success of the REMS? Please comment on the metrics that should be applied to measure the success of each of the components of the REMS (e.g., educational requirements) as well as metrics to assess the impact of the overall REMS on decreasing abuse and misuse of long acting opioids and extended release opioids while seeking to ensure that they remain available for patients who suffer daily from chronic pain.

III. Attendance and Registration

Register via email to *OpioidREMS@fda.hhs.gov* by providing complete contact information for each attendee (including name, title, affiliation, address, email address, and phone number(s)) by May 15, 2009. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Please send no more than two individuals from your organization. Registration on the first day of the meeting will be provided on a space available basis beginning at 8 a.m.

If you wish to make an oral presentation at the meeting, you must indicate this at the time of registration. FDA has included questions for comment in section II of this document. You should also identify by number each question you wish to address in your presentation. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. If you need special accommodations because of disability, please e-mail *OpioidREMS@fda.hhs.gov* at least 7 days before the meeting.

IV. Comments

Regardless of attendance at the public meeting, interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. To ensure consideration, submit comments by June 30, 2009. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts

Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 30 days after the meeting. A transcript will also be made available in either hard copy or on CD–ROM, upon submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: April 14, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–8992 Filed 4–17–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Amended Notice

The purpose of this notice is to inform the public that the National Institutes of Health (NIH) is cancelling the May 5, 2009 meeting of the NIH Blue Ribbon Panel to Advise on the Risk Assessment of the National Emerging Infectious Diseases Laboratories at Boston University Medical Center. The announcement for the May 5, 2009 meeting was previously published in the **Federal Register** on April 3, 2009 (74 FR 15296).

The meeting will be rescheduled and the new date for the meeting will be announced and published in the **Federal Register**.

Dated: April 14, 2009.

Kelly Fennington,

Special Assistant to the Acting Director, Office of Science Policy, National Institutes of Health.

[FR Doc. E9–9037 Filed 4–17–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood 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 Heart, Lung, and Blood Advisory Council.

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.

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 Heart, Lung, and Blood Advisory Council.

Date: June 10, 2009.

Open: 8 a.m. to 12 p.m.

Agenda: To discuss program policies and issues.

Place: National Institutes of Health, Building 31, 31 Center Drive, C–Wing, Room 10, Bethesda, MD 20892.

Closed: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, C–Wing, Room 10, Bethesda, MD 20892.

Contact Person: Stephen C. Mockrin, Phd, Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7100, Bethesda, MD 20892, (301) 435–0260, *mockrins@nhlbi.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, drivers license, or passport) and to state the purpose of their visit.

Information is also available on the Institutes/Center's home page: *www.nhlbi.nih.gov/meetings/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 13, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–8903 Filed 4–17–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2009–0001]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; 30-day notice and request for comments; revision of a currently approved information collection; OMB No. 1660–0073; FEMA Form 089–10, Narrative Statement, and FEMA Form 089–11, Performance Reports, and FEMA Form 089–12, Extensions/Budget Changes, and FEMA Form 089–13, Memorandum of Agreement Revisions, and FEMA Form 089–14, Self Evaluations, and FEMA Form 089–15, Task Force Deployment Data.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission describes the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and includes the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before May 20, 2009.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 1800 South Bell Street, Arlington, VA 20598–3005, facsimile number (202) 646–3347, or e-mail address *FEMA–Information-Collections@dhs.gov.*

SUPPLEMENTARY INFORMATION:

Collection of Information

Title: National Urban Search and Rescue Grant Program.

Type of information collection: Revision of a currently approved information collection.

OMB Number: 1660–0073.

Form Titles and Numbers: FEMA Form 089–10, Narrative Statement, and FEMA Form 089–11, Performance Reports, and FEMA Form 089–12, Extensions/Budget Changes, and FEMA Form 089–13, Memorandum of Agreement Revisions, and FEMA Form 089–14, Self Evaluations, and FEMA Form 089–15, Task Force Deployment Data.

Abstract: The information collection activity is the collection of financial, program and administrative information for US&R Sponsoring Organizations relating to preparedness and response Cooperative Agreement awards. This information includes a narrative statement that FEMA uses to evaluate a grantee's proposed use of funds, progress reports to monitor overall progress on managing FEMA grant program, extension or change requests used to consider changing or extending the time or the performance period of the preparedness or response cooperative agreement, evaluation and information to assess and ensure operational readiness and a memorandum of agreement between DHS/FEMA and the Sponsoring Organizations of US&R task forces.

Affected Public: State, Local or Tribal Government.

Estimated Number of Respondents: 28.

Frequency of Response: Semi-annually.

Estimated Average Hour Burden per Respondent: 17 Hours.

Estimated Total Annual Burden Hours: 476 hours.

Estimated Cost: There are no start-up, operational or other costs associated with this information collection.

Larry Gray,

Director, Records Management Division, Office of Management, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. E9–9008 Filed 4–17–09; 8:45 am]

BILLING CODE 9110–69–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2009–0001]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; 30-day notice and request for comments; revision of a currently approved information collection; OMB No. 1660–0083; FEMA Form 116–0–1, Promissory Note, FEMA Form 085–0–1, Local Government Resolution Collateral Security, FEMA Form 090–0–1, Certification of Eligibility for Community Disaster Loans, and FEMA Form 090–0–2, Application for Community Disaster Loan.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the