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.