

areas of expertise and jurisdiction between the Agencies. This information will simplify and expedite the introduction of new and important medical technologies and techniques while maintaining safety and efficacy levels appropriate to the various technologies and devices.

During each session, members of the public may present oral comments related to the topic of that session. Specific questions for comment are listed in section III of this document. Individuals who are interested in giving an oral presentation during any of the sessions must indicate this interest at the time of registration and must also identify the session(s) at which they would like to present (see *Registration and Requests for Oral Presentation*). In order to keep each session focused on the topic at hand, each oral presentation should address only the topic specified for that session. Persons who wish to comment are free to submit written comments on any topic(s) to the open docket (see *Comments*). FDA and FCC will schedule speakers for each session as time permits.

In advance of the meeting, additional information, including a meeting agenda with a speakers' schedule for each session, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at <http://www.regulations.gov> and in the FDA and FCC public reference rooms listed previously. This information will also be available at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select the appropriate meeting from the list) and from <http://www.fcc.gov/workshops>.

### III. Questions for Comment

FDA and FCC are planning to focus the public meeting on the following topics:

1. Data integrity and reliability issues arising from the use of allocated spectrum, the use of unlicensed devices, and the use of commercial networks and applications, and needs, uses, and risks for 'medical-grade' wireless technology and communications.

2. Medical device and system security issues—inadvertent and intentional intrusion—nonfunction and malfunction.

3. Trends in medical devices using allocated spectrum and using unlicensed operation, and medical devices and applications using commercial networks. Consideration of various wireless networking scenarios and use cases.

4. Risks Management:

- The need to define levels of "criticality" of device function that can be used for determining reliability requirements.
- Environmental factors and delivery setting—hospitals, users, clinics, home, travel, etc.

5. Views on current FDA and FCC regulatory requirements:

- Relationship between FDA approval/clearance and FCC certification of applications, post market and compliance requirements.

Each of the previous topics will cover:

1. Defining topics and scope;
2. Identifying the needs, goals, and stakeholders; and
3. Recommendations.

FDA and FCC are seeking comments on the topics and soliciting suggestions on alternate or additional topics that commenters deem closely related. All comments and suggestions will be considered with the constraint of completing the workshop in no more than 2 days. To be considered, topics proposed must be relevant to the objective and intent of the workshop.

### IV. Transcripts

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857 or at the Federal Communications Commission, Reference Information Center, 445 12th St. SW., rm. CY-A257, Washington, DC 20554, Monday through Thursday, between the hours of 8 a.m. and 4:30 p.m. and on Fridays between 8 a.m. and 12 noon, approximately 15 working days after the public meeting at a cost of 10 cents per page. A transcript of the public meeting will be available on the Internet at <http://www.regulations.gov>.

Dated: June 14, 2010.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Effectiveness Research on Smoking Cessation in Hospitalized Patients.

*Date:* June 22-23, 2010.

*Time:* 6 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Shelley S. Sehnert, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7206, Bethesda, MD 20892-7924. 301-435-0303. [ssehnert@nhlbi.nih.gov](mailto:ssehnert@nhlbi.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. 93.233, 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: June 11, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health and Human Development; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract