

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 Eye Institute Special Emphasis Panel, Immunosuppression for Eye Diseases.

*Date:* April 20, 2010.

*Time:* 3 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Eye Institute, 5635 Fishers Lane, 1300, Bethesda, MD 20892.

*Contact Person:* Samuel Rawlings, PhD, Chief, Scientific Review Branch, Division of Extramural Research, National Eye Institute, 5635 Fishers Lane, Suite 1300, MSC 9300, Bethesda, MD 20892-9300, 301-451-2020, [rawlings@nei.nih.gov](mailto:rawlings@nei.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. 93867, Vision Research, National Institutes of Health, HHS)

Dated: April 8, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-8846 Filed 4-20-10; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

A Special Emphasis Panel is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and Quality (AHRQ), and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly-scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public in accordance with the

Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications for the Recovery Act 2009 Limited Competition: AHRQ Clinical and Health Outcomes Initiative in Comparative Effectiveness (CHOICE) Grants (R01) applications are to be reviewed and discussed at this meeting. These discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure under the above-cited statutes.

*SEP Meeting on:* Recovery Act 2009 Limited Competition: AHRQ Clinical and Health Outcomes Initiative in Comparative Effectiveness (CHOICE) Grants (R01).

*Date:* April 28-30, 2010 (Open on April 28 from 8 a.m. to 8:15 a.m. and closed for the remainder of the meeting).

*Place:* Doubletree Bethesda Hotel & Executive Meeting Center, 8120 Wisconsin Avenue, Conference Room TBD, Bethesda, Maryland 20852.

*Contact Person:* Anyone wishing to obtain a roster of members, agenda or minutes of the nonconfidential portions of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Room 2038, Rockville, Maryland 20850, Telephone (301) 427-1554.

Agenda items for this meeting are subject to change as priorities dictate.

This notice is published less than 15 days in advance of the meeting date due to logistical difficulties.

Dated: April 13, 2010.

**Carol M. Clancy,**

*Director.*

[FR Doc. 2010-9035 Filed 4-20-10; 8:45 am]

**BILLING CODE 4160-90-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0202]

#### Medical Device Use in the Home Environment: Implications for the Safe and Effective Use of Medical Device Technology Migrating Into the Home; Public Workshop; Request for Comments

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

**ACTION:** Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled Medical Device Use in the Home Environment: Implications for the Safe and Effective Use of Medical Device Technology Migrating Into the

Home. The purpose of the workshop is to solicit information from healthcare providers, academics, human factors experts, medical device manufacturers and distributors, professional societies, patient advocacy groups, patients, and caregivers, on the challenges surrounding medical device technology in the home environment. FDA seeks input and comments on a number of identified topics related to medical device home use.

*Dates and Times:* The public workshop will be held on May 24, 2010, from 7:30 a.m. to 5 p.m. Persons interested in attending and/or participating in the workshop must register by 5 p.m. on May 17, 2010. Submit written or electronic comments by June 30, 2010.

*Location:* The public workshop will be held at the Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's front desk telephone number is 301-589-5200.

*Contact Person:* Mary Brady, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2320, Silver Spring, MD 20993-0002, e-mail: [Mary.Brady@fda.hhs.gov](mailto:Mary.Brady@fda.hhs.gov) (preferable), 301-796-6089.

*Registration and Requests for Oral Comments:* If you wish to attend the public meeting, you must register online at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select the appropriate meeting from the list). Please provide complete contact information for each attendee, including name, title, organization or company, address, e-mail, and telephone number. Registrations must be submitted by May 17, 2010.

If you wish to make an oral comment during general sessions of the public workshop (see section III of this document), you must indicate this in your registration. Please also identify which topics you wish to address in your oral comment. Topics for discussion are listed in section II of this document. FDA will do its best to accommodate all persons who wish to make oral comments during the general sessions. However, FDA strongly recommends that you provide written or electronic comments as instructed in this document to ensure that your comments are captured. Please refer to the section entitled *Comments* for instructions on submitting written or electronic comments.

Registration is free and will be on a first-come, first-served basis. Early registration is encouraged because seating is limited. There will be no onsite registration.

If you need special accommodations due to a disability (such as wheelchair access or a sign language interpreter), please notify Ian Chan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3313, Silver Spring, MD 20993-0002, e-mail: [Ian.Chan@fda.hhs.gov](mailto:Ian.Chan@fda.hhs.gov) (preferable); 301-796-6658 at least 7 days before the public workshop (no later than May 17, 2010).

**Comments:** The goal of this public workshop is to gain a greater understanding of medical device use in the home and to solicit feedback from the public regarding how the Center for Devices and Radiological Health (CDRH) should be reviewing and monitoring these devices. The deadline for submitting comments related to this public workshop is June 30, 2010.

Regardless of attendance at the public workshop, interested persons may submit written or electronic comments on the topics listed in section II of this document. If you wish to comment in writing on a particular topic, please identify the topic that you are addressing before providing your response to the question. For example, your comment could take the following format:

“Topic 1—[Quote the topic].”

“Response—[Insert your response].”

You do not have to address every topic. For those topics pertaining to the prevalence of a particular need, problem, or scientific question, please provide data and/or references so that FDA can understand the basis for your comment, figures, and any assumptions that you used.

Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Electronic comments should be submitted to <http://www.regulations.gov>. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Assuring the safety and safe use of medical devices in the home is becoming an increasingly important public health issue. The aging of the U.S. population and shifts toward shorter hospital stays continue to make home healthcare more common. With these trends, a significant number of medical devices, including infusion pumps, ventilators, and wound care

therapies, are now being used in the home.

Home healthcare can provide significant benefits to patients, in terms of both quality of life and cost of care. However, because the home environment is fundamentally different from the clinical environment, home use of medical devices presents unique challenges, many of which have the potential to impact patient safety. Home medical care is often provided by lay caregivers, who may not have received proper training in the operation of the medical devices on which their loved ones rely. Moreover, many medical devices that are currently used in the home were not designed for use by lay caregivers or outside of a controlled clinical environment.

FDA's CDRH has announced its Medical Device Home Use Initiative, a multi-pronged effort to support the safety and safe use of medical devices in the home. The goal of the initiative is to support safe, high-quality home healthcare and facilitate the development of medical devices that are capable of meeting patients' needs in the home. This public workshop is one of several steps CDRH is taking to provide greater assurance of the safety and safe use of medical device technology used in the home setting. Additional information on the benefits and challenges associated with the use of devices in the home, other actions FDA is taking as a part of its home use device initiative, as well as an agency white paper is available at [www.fda.gov/homeusedevices](http://www.fda.gov/homeusedevices).

##### **II. Why Are We Holding This Public Workshop?**

The purpose of the public workshop is to solicit expert input on topics related to the safe and effective use of medical device technology in the home environment. The workshop will highlight steps that can be taken to assure that medical devices are safe and effective when used by lay people in the home. The information gathered in the workshop will help guide future efforts by FDA's CDRH to address the growing use of medical devices in the home environment. Some of this information may be incorporated into guidance document or other agency actions. Accordingly, FDA looks forward to participation and written or electronic comments from manufacturers and distributors, innovators, and organizations that either market or have in development technologies that could be used in the home environment.

FDA will solicit feedback on:

1. The agency's current working definition of “home use” as a medical

device that: Is intended for users in a non-clinical or transitory environment; is managed partly or wholly by the user; requires adequate labeling for use; and may require training by a licensed healthcare provider in order to be used safely and effectively;

2. The unique risks in the home environment that need to be factored into device design;

3. The unique characteristics of end users in the home environment that need to be factored into device design;

4. The challenges and limitations associated with tracking medical devices in the home for purposes of safety notices and recalls, as well as potential solutions to these challenges; and

5. What elements, from the user perspective, should be incorporated into device labeling to help lay users understand and use a medical device safely in the home.

FDA intends to discuss and expand on these topics during the breakout group discussions at the workshop.

##### **III. What Will Be the Format for the Workshop?**

The workshop will begin with a general session. The presentations during this session will provide topics for a set of breakout groups that will meet in the afternoon. Each of the breakout group discussion sessions will be led and moderated by an expert panel. Each breakout session will begin with a presentation by an invited speaker, describing the issues of concern in the specific topic area. This will be followed by a moderated question and comment session, including both pre-specified questions posed to the assembled group and any questions that arise during the workshop discussions. Breakout group participation will be limited by space and will be available on a first-come, first-served basis. At the conclusion of the day's breakout group discussions, the general session will reconvene. When the general session reconvenes, each breakout group will report to the general session the results of its discussion.

##### **IV. Where Can I Find Out More About FDA's Medical Device Home Use Initiative?**

Information on the public workshop, registration information, the agenda, lodging, and other relevant information will be posted, as it becomes available, on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/Workshops/Conferences/default.htm> (select the appropriate meeting from the list). Background information regarding

FDA's Medical Device Home Use Initiative can be found at [www.fda.gov/homeusedevices](http://www.fda.gov/homeusedevices).

#### V. Additional Information

Following the meeting, a report of the workshop and the information presented will be available on the meeting Web page which can be found at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select the appropriate meeting from the list).

Dated: April 16, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-9287 Filed 4-20-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-1874-DR; Docket ID FEMA-2010-0002]

#### Virginia; Amendment No. 2 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the Commonwealth of Virginia (FEMA-1874-DR), dated February 16, 2010, and related determinations.

**DATES:** *Effective Date:* April 13, 2010.

**FOR FURTHER INFORMATION CONTACT:**

Peggy Miller, Recovery Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the Commonwealth of Virginia is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of February 16, 2010.

Craig, Roanoke, and Tazewell Counties and the Independent Cities of Fredericksburg and Roanoke for Public Assistance.

Craig, Roanoke, and Tazewell Counties and the Independent Cities of Fredericksburg and Roanoke for emergency protective measures (Category B), including snow assistance, under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora

Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2010-9122 Filed 4-20-10; 8:45 am]

**BILLING CODE 9111-23-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2010-0274]

#### Towing Safety Advisory Committee; Vacancies

**AGENCY:** Coast Guard, DHS.

**ACTION:** Request for applications.

**SUMMARY:** The Coast Guard seeks applications for membership on the Towing Safety Advisory Committee (TSAC). This Committee advises the Coast Guard on matters relating to shallow-draft inland and coastal waterway navigation and towing safety. **DATES:** Completed application forms should reach us on or before May 21, 2010.

**ADDRESSES:** Application forms are available for download on the Advisory Committee's Web site at <http://homeport.uscg.mil/tsac>. Look for the *Application for Committee Membership ACM* under "General Information". You may also request an application form be e-mailed or sent to you by writing to Commandant (CG-5222)/TSAC, U.S. Coast Guard, 2100 Second St., SW., STOP 7126, Washington, DC 20593-7126; calling 202-372-1427; or e-mail to [Michael.J.Harmon@uscg.mil](mailto:Michael.J.Harmon@uscg.mil).

Also a copy of the application form, as well as this notice, is available in our online docket, USCG-2010-0274, at <http://www.regulations.gov>. Send your completed application to Michael J. Harmon, the Alternate Designated Federal Officer (ADFO) at the street address above.

**FOR FURTHER INFORMATION CONTACT:** Michael J. Harmon, ADFO of Towing Safety Advisory Committee (TSAC); telephone 202-372-1427; fax 202-372-

1926; or e-mail at [Michael.J.Harmon@uscg.mil](mailto:Michael.J.Harmon@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Towing Safety Advisory Committee (TSAC) ("Committee") is a Federal advisory committee under 5 U.S.C. App. (Pub. L. 92-463). It was established under authority of 33 U.S.C. 1231a and advises the Secretary of Homeland Security on matters relating to shallow-draft inland and coastal waterway navigation and towing safety. This advice also assists the Coast Guard in formulating the position of the United States in advance of meetings of the International Maritime Organization.

The Committee meets at least twice a year around towing industry populations and in the Washington DC area. It may also meet for extraordinary purposes. Subcommittees and workgroups may conduct intersessional telephonic meetings when necessary for specific tasking. The 16 members include:

- 7 representatives from the Barge and Towing industry (reflecting a regional geographical balance);
- 1 member from the Offshore Mineral and Oil Supply Vessel industry;
- 2 members each from the following sectors:

- Maritime Labor;
- Shippers (of whom one will be engaged in the shipment of oil or hazardous materials by barge);
- Port District Authorities or Terminal Operators;
- The General Public.

*The Coast Guard is currently considering applications for six positions that will become vacant on September 30, 2010:*

- 3 from the Barge and Towing industry;
- 1 from the Port District Authorities or Terminal Operators;
- 1 from Maritime Labor;
- 1 from Shippers (who must represent engagement in the shipment of oil or hazardous materials by barge).

To be eligible, applicants should have expertise, knowledge, and experience relative to the position in the towing industry, marine transportation, or business operations associated with shallow-draft inland and coastal waterway navigation and towing safety. Registered lobbyists are not eligible to serve on Federal advisory committees. Registered lobbyists are lobbyists required to comply with provisions contained in the Lobbying Disclosure Act of 1995 (Pub. L. 110-81, as amended). Each member serves for a term of three years. Members may be considered to serve consecutive terms. All members serve at their own expense