

Committee. The list of research topics to be discussed at the meeting will be available on the following Web site prior to the meeting: [http://www.cms.hhs.gov/mcd/index\\_list.asp?list\\_type=mcac](http://www.cms.hhs.gov/mcd/index_list.asp?list_type=mcac). We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

### III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your State-issued driver's license), address, organization, telephone, fax number(s), and e-mail address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified the seating capacity has been reached.

### IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means of all persons entering the building. We note that all

items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

**Note:** Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

**Authority:** 5 U.S.C. App. 2, section 10(a). (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 24, 2009.

**Barry M. Straube,**

*Chief Medical Officer and Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.*

[FR Doc. E9-20844 Filed 8-27-09; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0664]

### Blood Establishment Computer Software: Understanding What to Include in a 510(k) Submission; 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 "Blood Establishment Computer Software: Understanding What to Include in a 510(k) Submission." The purpose of the public workshop is to educate industry on the laws and regulations for medical devices that are applicable to Blood Establishment Computer Software (BECS), including requirements for the content of a 510(k) submission. The public workshop will feature presentations and panel discussions led by FDA and other experts in software quality engineering.

**Date and Time:** The public workshop will be held on November 4, 2009, from

8:30 a.m. to 5 p.m. and November 5, 2009, from 8:30 a.m. to 12 noon.

**Location:** The public workshop will be held at The Universities at Shady Grove Conference Center, Bldg. II, multipurpose room, 9630 Gudelsky Dr., Rockville, MD 20850.

**Contact Person:** Rhonda Dawson, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, suite 550N, Rockville, MD 20852-1448, 301-827-6129, FAX: 301-827-2843, e-mail: [rhonda.dawson@fda.hhs.gov](mailto:rhonda.dawson@fda.hhs.gov).

**Registration:** Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone, and fax numbers) to the contact person by October 16, 2009. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** BECS is a device used in the prevention of disease in humans, by identifying unsuitable donors and preventing the release of infectious or otherwise harmful blood and blood components for transfusion or for further manufacturing use. Facilities that manufacture and distribute BECS are subject to device provisions of the Federal Food, Drug, and Cosmetic Act (the act), including premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) and applicable regulations at 21 CFR 807, subpart E. The public workshop will consist of a series of presentations, question-and-answer sessions, and a panel discussion on the following topics:

- The history and legal framework of BECS regulation in the United States;
- Content of 510(k) submissions, applicable regulations, and guidance;
- Common challenges in obtaining 510(k) clearance;
- FDA-recognized software standards;
- General software quality engineering;
- Transfusion safety management systems (blood administration software);
- Virtualization; and
- Wireless technology.

**Transcripts:** Transcripts of the public workshop 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,

approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm>.

Dated: August 21, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-20781 Filed 8-27-09; 8:45 am]

**BILLING CODE 4160-01-S**

## 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. Cardiopulmonary and Hematology Grant Opportunities (ARRA).

*Date:* September 2, 2009.

*Time:* 12 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call)

*Contact Person:* Robert Blaine Moore, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7213, Bethesda, MD 20892. 301-594-8394. [mooreb@nhlbi.nih.gov](mailto:mooreb@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; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: August 21, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-20775 Filed 8-27-09; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer 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 Cancer Institute Initial Review Group; Subcommittee J—Population and Patient-Oriented Training.

*Date:* October 28, 2009.

*Time:* 7:45 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Monaco Alexandria, 480 King Street, Alexandria, VA.

*Contact Person:* Ilda M. Mckenna, PhD, Scientific Review Officer, Research Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8111, Bethesda, MD 20892, 301-496-7481, [mckennai@mail.nih.gov](mailto:mckennai@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 21, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-20782 Filed 8-27-09; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

#### Agency Information Collection Activities: Form I-485 and Supplements A and E, Revision of a Currently Approved Information Collection; Comment Request

**ACTION:** 30-Day Notice of Information Collection Under Review: Form I-485 and Supplements A and E, Application to Register Permanent Residence or Adjust Status; OMB Control No. 1615-0023.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on June 11, 2009, at 74 FR 27811, allowing for a 60-day public comment period. USCIS did not receive any comments for this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until September 28, 2009. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), USCIS Desk Officer. Comments may be submitted to: USCIS, Chief, Regulatory Products Division, Clearance Office, 111 Massachusetts Avenue, Washington, DC 20529-2210. Comments may also be submitted to DHS via facsimile to 202-272-8352 or via e-mail at [rfs.regs@dhs.gov](mailto:rfs.regs@dhs.gov), and to OMB USCIS Desk Officer via facsimile at 202-395-5806 or via e-mail at [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov).

When submitting comments by e-mail please make sure to add OMB Control Number 1615-0023. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the