context of what is known about small clinical trials across medical products (e.g. drugs, biologics, and devices).

Date and Time: The course will be held on November 27, 2012, from 8 a.m. to 5 p.m., and November 28, 2012, from 8 a.m. to 3 p.m.

Location: The course will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Section A, Silver Spring, MD 20993–0002. Entrance for course participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* A live Web cast will be made available for FDA participants only. For participants who cannot attend the live course, a recorded Web cast will be made available after the course.

Contact: For information regarding this notice: Francesca Joseph, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5264, Silver Spring, MD 20993–0002, 301–796–6805, FAX: 301–847–8621, email: *Francesca.Joseph@fda.hhs.gov.*

For information regarding the course and registration: Megan McNamee, ICF International, 530 Gaither Rd., suite 500, Rockville, MD 20850, 301–407–6627, email: *Megan.Mcnamee@icfi.com.*

Registration: Interested participants may register for this course at the following Web site: *https://events-support.com/events/FDA–NIH_Science_Small_Clinical_Trials.*

If you need sign language interpretation during this course, please contact Francesca Joseph at *Francesca.Joseph@fda.hhs.gov* by October 26, 2012.

The FDA–NIH Science of Small Clinical Trials Course is presented by FDA's Office of Orphan Product Development, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health; the NIH Office of Rare Disease Research, National Center for Advancing Translational Sciences; and will also include participation from outside experts in the field. This educational event will consist of live presentations provided by FDA experts from various Centers and Offices, as well as from outside experts. It will also include case studies of regulatory trials and interactive panel discussions. The course will be recorded for subsequent posting on FDA's Web site.

(FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Dated: October 4, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–24977 Filed 10–10–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Neurological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 1, 2012, from 8 a.m. to 6 p.m.

Location: Hilton, Washington, DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900.

Contact Person: LCDR Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993–0002, 301–796–3805, *Avena.Russell@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On November 1, 2012, the committee will discuss current knowledge about the safety and effectiveness of the CoAxia NeuroFlo Catheter device for the intended use of diverting cardiac output to the cerebral vasculature via partial occlusion of the descending aorta, including in patients with acute ischemic stroke within 14 hours of symptom onset.

The CoAxia NeuroFlo Catheter is a 7F multi-lumen device with two balloons mounted near the distal tip. The proximal end has a multi-port manifold which provides access for the guidewire, monitoring of blood pressure, and independent inflation of the individual balloons. The device is placed in the descending aorta. On March 30, 2005, a Humanitarian Device Exemption application for the CoAxia NeuroFlo Catheter was approved for the following indication for use:

> The CoAxia NeuroFlo Catheter is intended for the treatment of cerebral ischemia resulting from symptomatic vasospasm following aneurismal subarachnoid hemorrhage (SAH), secured by either surgical or endovascular intervention for patients who have failed maximal medical management.

Of note, the CoAxia Neuroflo Catheter is identical in design to the Coaxia FloControl which is currently cleared for the following general indications for use:

- The CoAxia FloControl Catheter is intended for use in selectively stopping or controlling flow in the peripheral vasculature (K023914).
- The CoAxia FloControl Catheter is intended for use in selectively stopping or controlling flow in the peripheral vasculature, which includes the descending aorta (K090970).

CoAxia has submitted a de novo application for the NeuroFlo Catheter for the following indication:

> The CoAxia NeuroFlo Catheter is intended for use in diversion of cardiac output via partial occlusion of the descending aorta, including patients with acute ischemic stroke within 14 hours of symptom onset. The CoAxia NeuroFlo Catheter is also intended for use in selectively stopping or controlling blood flow in the peripheral vasculature, which includes the descending aorta.

FDA is convening this committee to seek expert scientific and clinical opinion on the risks and benefits of this device based on the available premarket and postmarket data. In particular, the panel will be asked to discuss the safety and effectiveness data from the ''Safety and Efficacy of NeuroFlo Technology in Ischemic Stroke (SENTIS)'' clinical trial

as they relate to the proposed indications for use.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 16, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 5, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 9, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Ann Marie Williams, Committee Management Staff, 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 3, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–24974 Filed 10–10–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; 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: Office of Research Infrastructure Programs Special Emphasis Panel; Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities, Special Emphasis Panel.

Date: November 7–8, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Martha F. Matocha, Ph.D., Scientific Review Officer, Office of Grants Management & Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Blvd., Dem. 1, Room 1070, Bethesda, MD 20892–4874, 240–271–4890, *matocham@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: October 4, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–24939 Filed 10–10–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Amended Notice of Meeting

Notice is hereby given of a change in the information provided in the **Federal Register** of the Council of Councils, October 29, 2012, 11 a.m. to October 29, 2012, 1 p.m., National Institutes of Health, Building 1, 1 Center Drive, Wilson Hall, Bethesda, MD, 20892 which was published in the **Federal Register** on October 3, 2012, 77FR60445.

This notice is being amended to correct the room number for the Executive Secretary to Room 260 and to remove statements on the original notice that do not apply to closed meetings. Since the entire meeting will be closed to the public in accordance with provisions set forth in sections 552(b)(c)(4) and 552b(c)(9)(B), the agenda and proposals will not be posted on the Council of Councils home page. The public procedures for filing comments or attending the meeting were also included in error.

Dated: October 4, 2012.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–24940 Filed 10–10–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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