unable to attend in person, FDA will provide a Webcast to the meeting. Additional information about the Webcast location will be posted on the Web page, http://www.fda.gov/Drugs/NewsEvents/ucm356526.htm, prior to December 4, 2013.

Any person requiring special accommodations to attend the hearing should direct those needs to the contact persons (see Contact Persons) at least 7 days in advance.

IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Center for Drug Evaluation and Research.

Under §15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA’s policy and procedures for electronic media coverage of FDA’s public administrative proceedings (21 CFR part 10, subpart C). Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA’s public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in §15.30(b) (see section III of this document for more details). To the extent that the conditions for the hearing as described in this document conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in §15.30(h).

V. Request for Comments

Regardless of attendance at the public hearing, interested persons may submit either electronic comments to http://www.regulations.gov or written comments to the Division of Dockets Management (see Comments). Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management by March 4, 2014. You should annotate and organize your comments to identify the specific questions identified by the topic to which they refer. It is only necessary to send one set of comments. All comment submissions should be marked 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, and will be posted to the docket at http://www.regulations.gov.

VI. References

The following references have been placed on display in the Division of Dockets Management (see Comments) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at http://www.regulations.gov.


Dated: September 12, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Center for Scientific Review Advisory Council.

The meeting will be open to the public, 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.

Name of Committee: Center for Scientific Review Advisory Council.
Date: October 28, 2013.
Time: 8:00 a.m. to 4:00 p.m.
Agenda: Provide advice to the Director, Center for Scientific Review (CSR), on matters related to planning, execution, conduct, support, review, evaluation, and receipt and referral of grant applications at CSR.
Place: National Institutes of Health, Room 3091, 6701 Rockledge Drive, Bethesda, MD 20892.
Contact Person: Donald L. Schneider, Ph.D., Senior Advisor to the Director, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3030, MSC 7776, Bethesda, MD 20892, (301) 435-1111, schneiderd@csr.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into NIH buildings. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver’s license, or passport) and to state the purpose of their visit.

Information is also available on the Institute’s/Center’s home page: http://public.csr.nih.gov/about csr/CSROrganization/Pages/CSRAC.aspx, where an agenda and any additional information for the meeting will be posted when available.


Dated: September 12, 2013.

Carolyn A. Baum,
Program Officer, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meetings

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 Institute of Child Health and Human Development Special Emphasis Panel, ADD Health Renewal.
Date: October 9, 2013.
Time: 11:00 a.m. to 2:00 p.m.
Agenda: To review and evaluate grant applications.
Date: October 1, 2013.
Time: 2:00 p.m. to 4:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

**Conflict:** The meeting will be open to the public, 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.

**Name of Committee:** National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
**Contact Person:** Michele C. Hindi-Alexander, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892, 301–435–8382, hindia@email.nih.gov.

**Name of Committee:** National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
**Contact Person:** Anshumali Chaudhari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435–1210, chaudhaa@csr.nih.gov.

**Name of Committee:** National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
**Contact Person:** Jane A. Doussard-Roosevelt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435–4445, doussar@csr.nih.gov.

**Name of Committee:** National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
**Contact Person:** Carolyn A. Baum, Program Analyst, Office of Federal Advisory Committee Policy.

**Name of Committee:** National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
**Contact Person:** Melanie J. Gray, Program Analyst, Office of Federal Advisory Committee Policy.