applied the identified criteria in making recommendations for additional disease areas to consider.

FDA also welcomes public comment on the criteria for disease area selection. These criteria include the following:

- Disease areas that are chronic, symptomatic, or affect functioning and activities of daily living;
- Disease areas that reflect a range of severity;
- Disease areas for which aspects of the disease are not formally captured in clinical trials;
- Disease areas that have a severe impact on identifiable subpopulations (such as children or the elderly);
- Disease areas that represent a broad range in terms of size of the affected population; or
- Disease areas for which there are currently no therapies or very few therapies, or the available therapies do not directly affect how a patient feels, functions, or survives.

FDA will consider the public comments received at the public meeting and through the docket and post the set of disease areas for FY 2013–2015 on the FDA Web site. By the end of FY 2015, FDA will initiate a public process for determining the list of disease areas for FY 2016–2017.

III. Public Meeting

FDA is holding a public meeting that will begin FDA’s patient-focused drug development initiative in PDUFA V. The purpose of this meeting will be to obtain public comment on the preliminary list of potential disease areas and the criteria used to develop the list. In addition, recognizing that there are many more disease areas than can be addressed in the 20 planned FDA meetings for PDUFA V, FDA will also discuss strategies that have already been pursued by patient and other public stakeholder collaborations outside of FDA to address the types of questions being considered under the PDUFA patient-focused drug development effort, to review lessons learned and identify a roadmap that could be used by patient-focused private collaborations going forward.

If you wish to attend this meeting, please register by email to PatientFocused@fda.hhs.gov by October 18, 2012. Your email should contain complete contact information, including name, title, affiliation, address, email address, and phone number. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations.

Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of disability, please contact Andrea Tan (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the meeting.

Dated: September 14, 2012.

Leslie Kux,
Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 a meeting of the Division of Intramural Research Board of Scientific Counselors, NIAID.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Allergy and Infectious Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Division of Intramural Research Board of Scientific Counselors, NIAID.

Date: December 10–12, 2012.

Time: December 10, 2012, 7:45 a.m. to 6:25 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 50, 50 Center Drive, Room 1227/1233, Bethesda, MD 20892.

Date: December 11, 2012, 7 a.m. to 6:25 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 50, 50 Center Drive, Room 1227/1233, Bethesda, MD 20892.

Place: National Institutes of Health, Building 50, 50 Center Drive, Room 1227/1233, Bethesda, MD 20892.

Dated: September 18, 2012.

David Clary,
Program Analyst, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 National Cancer Institute Director’s Consumer Liaison Group.

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 Cancer Institute Director’s Consumer Liaison Group.

Date: October 25–26, 2012.

Time: 9 a.m. to 1 p.m.


Place: National Institutes of Health, Building 31, 31 Center Drive, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Kelli Marciel, Director, Office of Advocacy Relations, National Cancer Institute, National Institutes of Health, 31 Center Drive, Building 31, Room 10A28, Bethesda, MD 20892, 301–594–3194.

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 onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. 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: deainfo.nic.nih.gov/advisory/dclg/dclg.htm, where an agenda and any additional information for the meeting will be posted when available.

(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: September 18, 2012.

Melanie J. Gray,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–23382 Filed 9–21–12; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Risk, Prevention and Health Behavior.

Date: October 11, 2012.

Time: 2 p.m. to 5 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: Rebecca Henry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, 301–435–1717, henryry@mail.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 10–260: Global Infectious Disease Training Program.

Date: October 12, 2012.

Time: 9 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites DC Convention Center, 900 10th Street NW., Washington, DC 20001.

Contact Person: Kenneth M. Izumi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge, RM 3204, MSC 7808, Bethesda, MD 20892, 301–496–6980, izumikm@csr.nih.gov.

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Tumor Microenvironment Study Section.

Date: October 22, 2012.

Time: 8 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Angela Y. Ng, Ph.D., MBA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6200, MSC 7804, Bethesda, MD 20892, 301–435–1715, ngan@mail.nih.gov.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Nursing and Related Clinical Sciences Study Section.

Date: October 23–24, 2012.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Cheryl M. Corsaro, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).


Dated: September 18, 2012.

Melanie J. Gray,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–23384 Filed 9–21–12; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 meetings.

The meetings 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