• Comments submitted in response to the November 2010 public hearing notice can be found at *http://www.regulations.gov* using Docket No. FDA–2010–N–0477.

• Additional information regarding implementation of the BPCI Act is available at: *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/UCM215031*.

IV. Notification of Intent To Participate in Consultation Meetings

If you intend to participate in stakeholder consultation meetings regarding the development of recommendations for a user fee program for biosimilar and interchangeable biological product applications for FYs 2013 through 2017, please provide notification by e-mail to *BiosimilarsUserFeeProgram@fda.hhs.gov* by January 10, 2011. Your e-mail should contain complete contact information, including name, title, affiliation, address, e-mail address, telephone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting once FDA receives their notification.

Dated: December 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30713 Filed 12–7–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Data Collection Tool for Rural Health Community-Based Grant Programs (OMB No. 0915–0319)—[Revision]

On May 20, 2008, OMB approved the Agency's request for the collection of data related to program and clinical measures (OMB No. 0915–0319) and set an expiration date of May 31, 2011. The Agency is now proceeding to submit a revised package which will include program specific measures that are further aligned with the agency's updated clinical measures. These measures were modified based on the feedback received from grantees and to reflect ORHP and HRSA's current priorities and clarify certain measures across all 330A programs. In addition, these revisions will enhance data collection and analysis in an effort to strengthen the value of the data collection tool.

There are currently six rural health grant programs that operate under the authority of Section 301 of the Public Health Service (PHS) Act. These programs include: (1) Rural Health Care Services Outreach Grant Program (Outreach); (2) Rural Health Network Development Grant Program (Network Development); (3) Small Healthcare Provider Quality Grant Program (Quality); (4) Delta States Rural Development Network Grant Program (Delta); (5) Network Planning Grant Program and (6) Rural Health Workforce Development Grant Program. These grants are to provide for the expanded delivery of health care services, the planning and implementation of integrated health care networks, and the planning and implementation of quality improvement and workforce activities—all in rural areas.

For these programs, performance measures were drafted to provide data useful to the programs and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993. These measures cover the principal topic areas of interest to ORHP, including: (a) Access to care; (b) the underinsured and uninsured; (c) workforce recruitment and retention; (d) sustainability; (e) health information technology; (f) network development, and (g) health related clinical measures. Several measures will be used for all six programs. All measures will speak to the Office's progress toward meeting the goals set.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Rural Health Care Services Outreach Grant Program	111	1	111	2.75	305.25
Rural Health Network Development	49	1	49	2	98
Delta States Rural Development Network Grant Program	12	1	12	3	36
Small Health Care Provider Quality Improvement Grant Program	59	1	59	6	354
Network Development Planning Grant Program	30	1	30	1	30
Rural Health Workforce Development Program	20	1	20	1.75	35
Total	281		281		858.25

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: December 1, 2010.

Robert Hendricks,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–30894 Filed 12–7–10; 8:45 am]

BILLING CODE 4165–15–P

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 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 Allergy and Infectious Diseases Special Emphasis Panel. A Tolerance Approach to Xenotransplantation.

Date: January 20, 2011.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817.

Contact Person: Quirijn Vos, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIH/NIAID/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892. 301–451–2666. *qvos@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 2, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–30811 Filed 12–7–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye 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 National Advisory Eye Council.

The meeting will be open to the public as indicated below, 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.

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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Eye Council.

Date: January 20, 2011.

Open: 8:30 a.m. to 12 p.m.

Agenda: Following opening remarks by the Director, NEI, there will be presentations by the staff of the Institute and discussions concerning Institute programs.

Place: National Institutes of Health, 5635 Fishers Lane, Terrace Level Conference Center, Bethesda, MD 20892.

Closed: 1:15 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Terrace Level Conference Center, Bethesda, MD 20892.

Contact Person: Andrew P. Mariani, PhD, Executive Secretary, National Advisory Eye Council, National Eye Institute, National Institutes of Health. 301–451–2020. *amp@nei.nih.gov.*

Any person interested 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.

Information is also available on the Institute's/Center's home page: *http://www.nei.nih.gov,* where an agenda and any additional information will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: December 2, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–30812 Filed 12–7–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel Developing Implementation Packages for Evidenced-based HIV Prevention Intervention Materials for Drug Users (5563).

Date: December 14, 2010.

Time: 9:30 a.m. to 12 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401. (301) 435–1439. *lf33c.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: National Institute on Drug Abuse Special Emphasis Panel Rapid Portable Devices to Measure Drug Use (1206).

Date: December 20, 2010.

Time: 9:30 a.m. to 12 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive