

\$268,974,000. (Note: These numbers exclude the President's Emergency Plan for AIDS Relief NDAs; no investigational new drug (IND) review costs are included in this amount.) Twenty-nine of these applications (20 NDAs and 9 BLAs) received priority review, which would mean that the remaining 19 received standard reviews. Because a priority review compresses a review schedule that ordinarily takes 10 months into 6 months, FDA estimates that a multiplier of 1.67 (10 months divided by 6 months) should be applied to non-priority review costs in estimating the effort and cost of a priority review as compared to a standard review. This multiplier is consistent with published research on this subject which supports a priority review multiplier in the range of 1.48 to 2.35 (Ref. 1). The multiplier derived by FDA falls well below the midpoint of this range. Using FY 2014 figures, the costs of a priority and standard review are estimated using the following formula:

$$(29 \alpha \times 1.67) + (19 \alpha) = \$268,974,000$$

Where " α " is the cost of a standard review and " α times 1.67" is the cost of a priority review. Using this formula, the cost of a standard review for NME NDAs and BLAs is calculated to be \$3,989,000 (rounded to the nearest thousand dollars) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or \$6,662,000 (rounded to the nearest thousand dollars). The difference between these two cost estimates, or \$2,673,000, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2016 fee, FDA will need to adjust the FY 2014 incremental cost by the average amount by which FDA's average costs increased in the 3 years prior to FY 2015, to adjust the FY 2014 amount for cost increases in FY 2015. That adjustment, published in the **Federal Register** on August 3, 2015 (see 80 FR 46028 at 46029), is 2.0266 percent for the most recent year, not compounded. Increasing the FY 2014 incremental priority review cost of \$2,673,000 by 2.0266 percent results in an estimated cost of \$2,727,000 (rounded to the nearest thousand dollars). This is the rare pediatric disease priority review user fee amount for FY 2016 that must be submitted with a priority review voucher for a human drug application in FY 2016, in addition to any PDUFA fee that is required for such an application.

III. Fee Schedule for FY 2016

The fee rate for FY 2016 is set out in table 1:

TABLE 1—RARE PEDIATRIC DISEASE PRIORITY REVIEW SCHEDULE FOR FY 2016

Fee category	Fee rate for FY 2016
Application submitted with a rare pediatric disease priority review voucher in addition to the normal PDUFA Fee.	\$2,727,000

IV. Implementation of Rare Pediatric Disease Priority Review User Fee

Under section 529(c)(4)(A) of the FD&C Act, the priority review user fee is due (*i.e.* the obligation to pay the fee is incurred) when a sponsor notifies FDA of its intent to use the voucher. Section 529(c)(4)(B) of the FD&C Act specifies that the application will be considered incomplete if the priority review user fee and all other applicable user fees are not paid in accordance with FDA payment procedures. In addition, section 529(c)(4)(C) specifies that FDA may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section of the FD&C Act. Beginning with FDA's appropriation for FY 2015, the annual appropriation language states specifically that priority review user fees authorized by 21 U.S.C. 360n and 360ff (section 529 of the FD&C Act) shall be credited to this account, to remain available until expended." (Pub. L. 113–235, Section 5, Division A, Title VI).

The rare pediatric disease priority review fee established in the new fee schedule must be paid for any application that is received on or after October 1, 2015. In order to comply with this requirement, the sponsor must contact FDA before providing official notification of its intent to use the voucher.

FDA will issue an invoice to the sponsor who has incurred a rare pediatric disease priority review voucher fee when it receives the sponsor's notification of intent to use the voucher. The invoice will include instructions on how to pay the fee via wire transfer or check.

As noted in section II, if a sponsor uses a rare pediatric disease priority review voucher for a human drug application, the sponsor would incur the rare pediatric disease priority review voucher fee in addition to any PDUFA fee that is required for the application. The sponsor would need to follow

FDA's normal procedures for timely payment of the PDUFA fee for the human drug application.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested person between 9 a.m. and 4 p.m., Monday through Friday.

- Ridley, D. B., H. G. Grabowski, and J. L. Moe, "Developing Drugs for Developing Countries," *Health Affairs*, vol. 25, no. 2, pp. 313–324, 2006.

Dated: September 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24508 Filed 9–25–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of 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 Board of Scientific Counselors, NIDCD.

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)(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 ON DEAFNESS AND OTHER COMMUNICATION DISORDERS, 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: Board of Scientific Counselors, NIDCD.

Date: October 26–27, 2015.

Closed: October 26, 2015, 8:00 a.m. to 8:30 a.m.

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

Place: National Institutes of Health, Porter Neuroscience Research Center, Room 610, Building 35A Convent Drive, Bethesda, MD 20892.

Open: October 26, 2015, 8:30 a.m. to 8:45 a.m.

Agenda: Reports from the Institute staff.

Place: National Institutes of Health, Porter Neuroscience Research Center, Room 610, Building 35A Convent Drive, Bethesda, MD 20892.

Closed: October 26, 2015, 8:45 a.m. to 4:40 p.m.

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

Place: National Institutes of Health, Porter Neuroscience Research Center, Room 610, Building 35A Convent Drive, Bethesda, MD 20892.

Closed: October 27, 2015, 8:00 a.m. to 2:15 p.m.

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

Place: National Institutes of Health, Porter Neuroscience Research Center, Room 610, Building 35A Convent Drive, Bethesda, MD 20892.

Contact Person: Andrew J. Griffith, Ph.D., MD, Director, Division of Intramural Research, National Institute on Deafness and Other Communication Disorders, 35A Convent Drive, GF 103, Rockville, MD 20892, 301-496-1960, griffita@nidcd.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 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: <http://www.nidcd.nih.gov/about/groups/bsc/>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: September 23, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-24545 Filed 9-25-15; 8:45 am]

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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; NHLBI Summer Training R25 Review.

Date: October 20, 2015.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: YingYing Li-Smerin, MD, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7184, Bethesda, MD 20892-7924, 301-435-0277, lismerin@nhlbi.nih.gov. (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, National Institutes of Health, HHS)

Dated: September 22, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-24482 Filed 9-25-15; 8:45 am]

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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; SBIB Clinical Pediatric and Fetal Applications.

Date: October 21, 2015.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: John Firrell, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5118, MSC 7854, Bethesda, MD 20892, 301-435-2598, firrellj@csr.nih.gov.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Biostatistical Methods and Research Design Study Section.

Date: October 23, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Courtyard Gaithersburg Washingtonian Ctr, 204 Boardwalk Place, Gaithersburg, MD 20878.

Contact Person: Peter J. Kozel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, Bethesda, MD 20892, 301-435-1116, kozelp@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA-CA-15-006: Big Data to Knowledge (BD2K) Advancing Biomedical Science Using Crowdsourcing and Interactive Digital Media (UH2).

Date: October 23, 2015.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Kee Hyang Pyon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7806, Bethesda, MD 20892, pyonkh2@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Virology.

Date: October 26, 2015.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington DC, Dupont Circle, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: John C. Pugh, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1206, MSC 7808, Bethesda, MD 20892, (301) 435-2398, pughjohn@csr.nih.gov.