

August 30, 2007, and 76 FR 19376, April 7, 2011) is amended to reflect the restructuring of CDER, FDA. This reorganization is explained in Staff Manual Guides 1262.1, 1262.3, 1262, 31, 1262.32, 1262.4, 1262.41, 1262.42, 1262.43, 1262.44, 1262.5, 1262.51, 1262.52, 1262.53, 1262.6, 1262.61, and 1262.62. This reorganization includes establishing four Offices and their substructures under the Office of Compliance: Office of Drug Security, Integrity and Recalls (ODSIR), Office of Unapproved Drugs and Labeling Compliance (OUDLC), Office of Manufacturing and Product Quality (OMPQ), and Office of Scientific Investigations (OSI). ODSIR will consist of the Division of Import Operations and Recalls and the Division of Supply Chain Integrity. OUDLC will consist of the Division of Prescription Drugs and the Division of Non-Prescription Drugs and Health Fraud. OMPQ will consist of the Division of International Drug Quality, the Division of Domestic Drug Quality, the Division of Policy, Collaboration and Data Operations, and the Division of GMP Assessment. OSI will consist of the Division of Bioequivalence and Good Laboratory Practice Compliance, the Division of Good Clinical Practice Compliance, and the Division of Safety Compliance. Also included is the abolishment of the Division of Compliance Risk Management.

II. Delegations of Authority

Pending further delegation, directives or orders by the Commissioner of Food and Drugs or Center Director, CDER, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

Persons interested in seeing the complete Staff Manual Guide can find it on FDA's Web site at: <http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm>.

Dated: June 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 Child Health and Human Development, Special Emphasis Panel, ZHD1 DSR-L 50 1.

Date: July 20, 2011.

Time: 4:30 to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Dennis E. Leszczynski, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Rockville, MD 20852, 301-435-6884, leszczyd@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 20, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood 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 would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute, Special Emphasis Panel; Revision for Resuscitation Outcomes Center Randomized Clinical Trial.

Date: July 15, 2011.

Time: 11 a.m. to 2 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: William J. Johnson, PhD, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892-7924, 301-435-0725, johnsonwj@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute, Special Emphasis Panel. Studies to Identify Genetic Determinants of COPD.

Date: July 20, 2011.

Time: 2 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: Stephanie J. Webb, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892, 301-435-0291, stephanie.webb@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: June 20, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

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