

comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: June 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-15814 Filed 6-23-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Joint Meeting of the Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committees: Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 20, 2011, from 8 a.m. to 1 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301-589-5200.

Contact Person: Kristine T. Khuc, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, e-mail: GIDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product

area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The meeting will be open to the public from 8 a.m. to 9 a.m., unless public participation does not last that long; from 9 a.m. to 1 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information.

FDA generally makes background material available to the public no later than 2 business days before the meeting or follows other procedures to make such material available to the public. There is no background material that is publicly available for this meeting.

Procedure: On July 20, 2011, from 8 a.m. to 9 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 6, 2011. Oral presentations from the public will be scheduled between approximately 8 a.m. to 9 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 27, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 28, 2011.

Closed Committee Deliberations: On July 20, 2011, from 9 a.m. to 1 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). During this session, the committees will discuss the drug development program of an investigational gastroenterology drug.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kristine T. Khuc at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Dated: June 21, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011-15823 Filed 6-23-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0013]

Statement of Organizations, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has reorganized the Center for Drug Evaluation and Research (CDER), Office of Compliance. This reorganization includes the organizations and substructure components as listed in this document. This document is announcing availability of the Staff Manual Guide that explains the details of this reorganization.

FOR FURTHER INFORMATION CONTACT: Karen Koenick, Center for Drug Evaluation and Research (HFD-063), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301-796-4422.

I. Summary

The Statement of Organization, Functions, and Delegations of Authority for CDER (35 FR 3685, February 25, 1970, 60 FR 56605, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112,

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.

[FR Doc. 2011-15801 Filed 6-23-11; 8:45 am]

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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.

[FR Doc. 2011-15872 Filed 6-23-11; 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 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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