

guidance. Issuance of the new draft guidance constitutes a revision of a previously published draft guidance and fulfills a portion of the requirements of Public Law 112–144.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on developing drugs for the treatment of uncomplicated gonorrhea. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

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

Dated: June 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–14303 Filed 6–18–14; 8:45 am]

BILLING CODE 4160–01–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; Biological Data Management and Analysis.

Date: June 25, 2014.

Time: 10 a.m. to 12 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: Mark Caprara, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7844, Bethesda, MD 20892, 301–435–1042, capraramg@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; Single Cell Analysis.

Date: July 1–2, 2014.

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

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Amy L. Rubinstein, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5152, MSC 7844, Bethesda, MD 20892, 301–408–9754, rubinstein@csr.nih.gov.

Name of Committee: AIDS and Related Research Integrated Review Group; AIDS-associated Opportunistic Infections and Cancer Study Section.

Date: July 11, 2014.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The St. Regis Washington DC, 923 16th Street NW., Washington, DC 20006.

Contact Person: Eduardo A. Montalvo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435–1168, montalve@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Omnibus Solicitation of the NIH for Small Business.

Date: July 11, 2014.

Time: 10 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

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

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, henryrr@mail.nih.gov.

Name of Committee: AIDS and Related Research Integrated Review Group; HIV/AIDS Vaccines Study Section.

Date: July 15, 2014.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Row Hotel, 2015 Massachusetts Avenue NW., Washington, DC 20036.

Contact Person: Mary Clare Walker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, walkermc@csr.nih.gov.

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

Date: July 16–17, 2014.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Michael L. Bloom, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7804, Bethesda, MD 20892, 301–451–0132, bloomm2@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Nutrition, Obesity and Diabetes.

Date: July 16, 2014.

Time: 10 a.m. to 1 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: Nancy Sheard, SCD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046–E, MSC 7892, Bethesda, MD 20892, 301–408–9901, sheardn@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Shared Instrumentation: Flow Cytometry.

Date: July 16, 2014.

Time: 11 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: David Balasundaram, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, 301-435-1022, balasundaramd@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Genomics Shared Instrumentation.

Date: July 16, 2014.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Richard Panniers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892, (301) 435-1741, pannierr@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business PAR Panel: Safe and Effective Instruments and Devices for Use in Neonatal and Pediatric Care Settings.

Date: July 16, 2014.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

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: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Nephrology, Urology and Pharmacology.

Date: July 16, 2014.

Time: 2 p.m. to 4:30 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: Patricia Greenwel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301-435-1169, greenwep@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 12, 2014.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-14296 Filed 6-18-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; RFA Panel: Tobacco Control Regulatory Research.

Date: June 13, 2014.

Time: 4:30 p.m. to 6:30 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: Mark P. Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-435-1775, rubertm@csr.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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 12, 2014.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-14297 Filed 6-18-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Symposium on Assessing Exposures and Health Effects Related to Indoor Biomass Fuel Burning; Notice of Meeting and Registration Information

SUMMARY: The National Toxicology Program (NTP) announces a symposium on "Assessing Exposures and Health

Effects Related to Indoor Biomass Fuel Burning." The symposium will bring together researchers working in the area of indoor biomass fuel burning emissions and health effects to discuss the latest science, policy, and future directions. The meeting is open to the public. Registration is requested for attendance and required to access the webcast. Information about the meeting and registration are available at <http://ntp.niehs.nih.gov/go/41613>.

DATES: Meeting: August 18, 2014, from 8 a.m. to approximately 5 p.m. Eastern Daylight Time (EDT).

Registration for Meeting: Registration is open through August 4, 2014.

Registration to view the symposium via webcast is required.

ADDRESSES:

Meeting Location: Rodbell Auditorium, Rall Building, National Institute of Environmental Health Sciences (NIEHS), 111 T.W. Alexander Dr., Research Triangle Park, NC 27709.

Meeting Web page: The preliminary agenda and registration are at <http://ntp.niehs.nih.gov/go/41613>.

Webcast: The meeting will be webcast; the URL will be provided to those who register for viewing.

FOR FURTHER INFORMATION CONTACT:

Dr. Cynthia Rider, NTP Toxicologist, NIEHS, P.O. Box 12233, MD K2-12, Research Triangle Park, NC 27709. Telephone: 919-541-7638, email: cynthia.rider@nih.gov.

SUPPLEMENTARY INFORMATION:

Background: The burning of solid fuels (e.g., wood, charcoal, dung) for cooking and heat results in a significant global health burden. According to the World Health Organization, over 4 million premature deaths per year are attributed to indoor air pollution from inefficient use of solid fuels (<http://www.who.int/mediacentre/factsheets/fs292/en/>). Understanding the health effects associated with indoor air pollution is a priority for NIEHS and is one of the five focus areas of the NIEHS' World Health Organization Collaborating Centre for Environmental Health Sciences (<http://www.niehs.nih.gov/research/programs/geh/partnerships/index.cfm>).

Progress on this important public health challenge requires a concerted cross-disciplinary effort involving exposure scientists, toxicologists, epidemiologists, engineers, and public policy experts. Towards this goal, this symposium will bring together researchers working in the area of indoor biomass fuel burning emissions and health effects to discuss the latest science including topics ranging from advances in exposure measurement to