

**Instructions:** All submissions received must include the Docket No. FDA–2016–D–0643 for “Labeling for Biosimilar Products; Draft Guidance for Industry; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for

Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993–0002, 301–796–1042; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of April 4, 2016 (81 FR 19194), FDA published a notice with a 60-day comment period to request comments on the draft guidance for industry entitled “Labeling for Biosimilar Products.” FDA is extending the comment period for an additional 60 days, until August 2, 2016. The Agency believes that a 60-day extension will allow adequate time for interested persons to submit comments without compromising timely publication of the final guidance.

**II. Electronic Access**

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

Dated: May 31, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–13223 Filed 6–3–16; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Arthritis and Musculoskeletal and Skin 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:** Arthritis and Musculoskeletal and Skin Diseases Initial Review Group; Arthritis and Musculoskeletal and Skin Diseases Special Grants Review Committee.

**Date:** June 16–17, 2016.

**Time:** 7:00 p.m. to 5:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Rd., Bethesda, MD 20852.

**Contact Person:** Helen Lin, Ph.D., Scientific Review Officer, NIH/NIAMS/RB, 6701 Democracy Blvd., Suite 800, Plaza One, Bethesda, MD 20817, 301–594–4952, [linh1@mail.nih.gov](mailto:linh1@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: May 27, 2016.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016–13200 Filed 6–3–16; 8:45 am]

**BILLING CODE 4140–01–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; Member Conflicts and Continuous Submission: Ischemia and HDL.

*Date:* June 22–23, 2016.

*Time:* 10:00 a.m. to 2:00 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:* Natalia Komissarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301–435–1206, [komissar@mail.nih.gov](mailto:komissar@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Hematology and Vascular Biology.

*Date:* June 27–28, 2016.

*Time:* 10:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Anshumali Chaudhari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435–1210, [chaudhaa@csr.nih.gov](mailto:chaudhaa@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR PANEL: Innovative Therapies and Tools for Screenable Disorders in Newborns (R01, R21, R03).

*Date:* June 28, 2016.

*Time:* 11:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

*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](mailto:pannierr@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Immune Mechanism and Vaccine Development.

*Date:* June 29–30, 2016.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

*Contact Person:* Liying Guo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4016F, Bethesda, MD 20892, 301–435–0908, [lguo@mail.nih.gov](mailto:lguo@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Cardiovascular Sciences.

*Date:* June 29–30, 2016.

*Time:* 8:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* New Orleans Marriott, 555 Canal Street, New Orleans, LA 70130.

*Contact Person:* Margaret Chandler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 4126, MSC 7814, Bethesda, MD 20892, (301) 435–1743, [margaret.chandler@nih.gov](mailto:margaret.chandler@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR 16–064: R21 Grants for New Investigators to Promote Diversity in Health-Related Research.

*Date:* June 29, 2016.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

*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](mailto:greenwep@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflict: Biological Chemistry and Macromolecular Biophysics.

*Date:* June 29–30, 2016.

*Time:* 8:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Raymond Jacobson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5858, MSC 7849, Bethesda, MD 20892, 301–996–7702, [jacobsonrh@csr.nih.gov](mailto:jacobsonrh@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Medical Imaging Investigations.

*Date:* June 29, 2016.

*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 (Virtual Meeting).

*Contact Person:* Mehrdad Mohseni, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7854, Bethesda, MD 20892, 301–435–0484, [mohsenim@csr.nih.gov](mailto:mohsenim@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR13–309–311: Translational Research in Pediatric and Obstetric Pharmacology and Therapeutics.

*Date:* June 29, 2016.

*Time:* 1:00 p.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, [dianne.hardy@nih.gov](mailto:dianne.hardy@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Hormones, Stress and Sleep.

*Date:* June 29, 2016.

*Time:* 1:00 p.m. to 3:00 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:* Jasenka Borzan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 4214 MSC 7814, Bethesda, MD 20892–7814, 301–435–1787, [borzanj@csr.nih.gov](mailto:borzanj@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Interventions and Mechanisms for Addictions.

*Date:* June 29, 2016.

*Time:* 12:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Marc Boulay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, (301) 300–6541, [boulaymg@csr.nih.gov](mailto:boulaymg@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: May 31, 2016.

**Natasha M. Copeland,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016–13192 Filed 6–3–16; 8:45 am]

**BILLING CODE 4140–01–P**

## 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.

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*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR15–306: Lymphatics in Health and Disease in the Digestive System, Kidney and Urinary Tract.