

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Beclomethasone dipropionate.  
 Betamethasone dipropionate.  
 Betrixaban.  
 Ciprofloxacin.  
 Deferasirox.  
 Dexamethasone; Neomycin sulfate; Polymyxin b sulfate.  
 Epinephrine.  
 Ethinyl estradiol; Norethindrone acetate.  
 Finafloxacin.  
 Fluocinolone acetonide.  
 Loteprednol etabonate.  
 Mecamylamine hydrochloride.  
 Methscopolamine bromide.  
 Methylphenidate.  
 Metyrosine.  
 Moxifloxacin hydrochloride.  
 Nebivolol hydrochloride; Valsartan.  
 Nimodipine.  
 Nitisinone.  
 Omeprazole.  
 Rifapentine.  
 Ritonavir.  
 Sodium polystyrene sulfonate.  
 Triamcinolone acetonide.  
 Valbenazine tosylate.

### III. Drug Products for Which Revised Draft Product-Specific Guidances are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Abiraterone acetate.  
 Dapagliflozin propanediol; Metformin hydrochloride.  
 Diclofenac sodium.  
 Donepezil hydrochloride; Memantine hydrochloride.  
 Esomeprazole strontium.  
 Ethosuximide.  
 Glatiramer acetate.  
 Hydrocodone bitartrate.  
 Lansoprazole.  
 Latanoprost.  
 Leucovorin calcium.  
 Methylphenidate hydrochloride.  
 Morphine sulfate; Naltrexone hydrochloride.  
 Nisoldipine.  
 Oxycodone hydrochloride.  
 Ticagrelor.  
 Triamcinolone acetonide.

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to <https://www.regulations.gov> and enter Docket No. FDA-2007-D-0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR

10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

### IV. Electronic Access

Persons with access to the internet may obtain the draft guidances at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: July 18, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-15735 Filed 7-20-18; 8:45 am]

**BILLING CODE 4164-01-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, 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; PAR-17-031: Role of Age-Associated Metabolic Changes in Alzheimer's Disease.

*Date:* July 31, 2018.

*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 (Virtual Meeting).

*Contact Person:* Samuel C. Edwards, Ph.D., Chief, BDCN IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, [edwardss@csr.nih.gov](mailto:edwardss@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: July 17, 2018.

**Sylvia L. Neal,**

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

[FR Doc. 2018-15605 Filed 7-20-18; 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, 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; Urologic and Urogynecologic Applications.

*Date:* July 20, 2018.

*Time:* 10:00 a.m. to 11:00 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Ganesan Ramesh, Ph.D., Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, 301-827-5467, [ganesan.ramesh@nih.gov](mailto:ganesan.ramesh@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; PAR Panel: Review of Aging Applications.

*Date:* August 13, 2018.

*Time:* 10:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Samuel C. Edwards, Ph.D., Chief, BDCN IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, [edwardss@csr.nih.gov](mailto:edwardss@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA-RM18-018: Somatic Cell Genome Editing Dissemination and Coordinating Center (U24).

*Date:* August 16, 2018.

*Time:* 2:00 p.m. to 4:00 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:* Elena Smirnova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301-357-9112, [smirnova@csr.nih.gov](mailto:smirnova@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:* July 16, 2018.

**Natasha M. Copeland,**

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

[FR Doc. 2018-15606 Filed 7-20-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIAAA.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 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 Alcohol Abuse and Alcoholism, 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, NIAAA.

*Date:* October 2, 2018.

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

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

*Place:* National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5625 Fishers Lane, Bethesda, MD 20892.

*Contact Person:* George Kunos, M.D., Ph.D., Scientific Director, National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5625 Fishers Lane, Room 2s-24a Rockville, MD 20852 301-443-2069 [gkunos@mail.nih.gov](mailto:gkunos@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

*Dated:* July 17, 2018.

**Melanie J. Pantoja,**

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

[FR Doc. 2018-15610 Filed 7-20-18; 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, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 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 R13 Conference Review.

*Date:* August 2-3, 2018.

*Time:* 9:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Stephanie J. Webb, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892, 301-435-0291, [stephanie.webb@nih.gov](mailto:stephanie.webb@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. 93.233, 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:* July 17, 2018

**Michelle D. Trout,**

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

[FR Doc. 2018-15620 Filed 7-20-18; 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, 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 Opportunities for Collaborative Research at the NIH Clinical Center.

*Date:* August 9, 2018.

*Time:* 1:00 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, (Telephone Conference Call).

*Contact Person:* William J Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892-7924, (301-827-7938) [johnsonwj@nhlbi.nih.gov](mailto:johnsonwj@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)