

identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for “Draft Guidance on Methylphenidate Hydrochloride.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New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. 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:

Xiaoqiu Tang, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific guidances available to the public on FDA’s Web site at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of a new draft guidance for generic methylphenidate hydrochloride oral extended-release tablets.

FDA initially approved new drug application 018029 for RITALIN–SR (methylphenidate hydrochloride oral extended-release tablets) in March 1982. We are now issuing a new draft guidance for industry on methylphenidate hydrochloride oral extended-release tablets (“Draft Guidance on Methylphenidate Hydrochloride”).

In May 2016, KVK-Tech, Inc. (KVK-Tech) submitted a citizen petition requesting, among other things, that FDA not accept for filing any new ANDAs or approve any already received ANDAs for methylphenidate hydrochloride oral extended-release tablets unless certain BE criteria are met. FDA will consider any comments on the draft guidance on BE recommendations for generic methylphenidate hydrochloride oral extended-release tablets before responding to KVK-Tech’s citizen petition. (Docket No. FDA–2016–P–1247, available at <https://www.regulations.gov>).

The new draft guidance is being issued consistent with FDA’s good

guidance practices regulation (21 CFR 10.115). The new draft guidance, when finalized, will represent the current thinking of FDA on the design of BE studies to support ANDAs for methylphenidate hydrochloride oral extended-release tablets. It does not establish any rights for any person and is 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.

II. Electronic Access

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

Dated: October 17, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–22891 Filed 10–20–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Performance Review Board Members

Title 5, U.S.C. Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment of Performance Review Board Members be published in the **Federal Register**. The following persons may be named to serve on the Performance Review Boards or Panels, which oversee the evaluation of performance appraisals of Senior Executive Service members of the Department of Health and Human Services.

Employee Name

Barry, Daniel
Barlow, Amanda
Coughlin, Janis
Fantinato, Jessica
Gentile, John
Johnson, Jeffrey
Katz, Ruth
Kretschmaier, Michon
Lewis, Lisa
McDaniel, Eileen
Novy, Steve
Sample, Allen
Skeadas, Christos
Tobias, Constance
Weber, Mark

Dated: October 16, 2017.

Charles H. McEnerney III,

Director, Executive and Scientific Resources Division.

[FR Doc. 2017-22863 Filed 10-20-17; 8:45 am]

BILLING CODE 4151-17-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Division of Behavioral Health; Youth Regional Treatment Center Aftercare Pilot Project; Correction of Due Dates

AGENCY: Indian Health Service, HHS.

ACTION: Notice; correction of due dates.

SUMMARY: The Indian Health Service published a notice in the **Federal Register** (FR) on October 11, 2017, for the Fiscal Year 2018 Youth Regional Treatment Center Aftercare Pilot Project, Funding Announcement Number: HHS-2018-IHS-YRTC-0001. Several Key Dates have been modified. The *Application Due Date* is November 12, 2017 and the *Earliest Anticipated Start Date* is December 1, 2017.

FOR FURTHER INFORMATION CONTACT: Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2114; or the Division of Grants Management main line (301) 443-5204, or Fax: (301) 594-0899.

Correction

In the FR notice of October 11, 2017 (FR 2017-21786), the corrections are:

Key Dates

Under the heading *Key Dates*, the notice should include the dates for *Review Date*, *Signed Tribal Resolutions Due Date*, and *Proof of Non-Profit Status Due Date* should read as:

- *Review Date:* November 20-24, 2017.
- *Signed Tribal Resolutions Due Date:* November 12, 2017.
- *Proof of Non-Profit Status Due Date:* November 12, 2017.

The *Application Due Date* remains as November 12, 2017.

Project Period

Under Project Period, the sentence corrections reflects a start date of December 1, 2017:

- “The project period is for three years and will run consecutively from December 1, 2017 to October 31, 2020.”

Submission Dates

Under Submission Dates and time: “Eastern Daylight Time (EDT)” should

be used instead of “Eastern Savings Time (EST).”

Dated: October 13, 2017.

Michael D. Weahkee,

Assistant Surgeon General, U.S. Public Health Service, Acting Director, Indian Health Service.

[FR Doc. 2017-22864 Filed 10-20-17; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; 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: National Institute of Nursing Research Special Emphasis Panel; Palliative Care Research Cooperative.

Date: November 3, 2017.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Mario Rinaudo, MD, Scientific Review Officer, Office of Review, National Inst of Nursing Research, National Institutes of Health, 6701 Democracy Blvd. (DEM 1), Suite 710, Bethesda, MD 20892, 301-594-5973, mrinaudo@mail.nih.gov.

Name of Committee: National Institute of Nursing Research Special Emphasis Panel; Lasker Clinical Research Scholars Program.

Date: November 7, 2017.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Room 703, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Weiqun Li, MD, Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd., Room 710, Bethesda, MD 20892, (301) 594-5966, wli@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: October 18, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-22911 Filed 10-20-17; 8:45 am]

BILLING CODE 4140-01-P

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 a meeting of the NHLBI Special Emphasis Panel.

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; SPIROMICS Genomics and Informatics Center (U24).

Date: November 15, 2017.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Suite 7182, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, susan.sunnarborg@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: October 17, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-22908 Filed 10-20-17; 8:45 am]

BILLING CODE 4140-01-P