These collections of information 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 part 7, subpart C, have been approved under OMB control number 0910–0249. The collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485. The collections of information in 21 CFR part 803, regarding medical device reporting, have been approved under OMB control numbers 0910–0291, 0910–0437, and 0910–0471. The collections of information in 21 CFR part 806 have been approved under OMB control number 0910–0359. The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120. The collections of information in 21 CFR part 810, regarding medical device recall authority, have been approved under OMB control number 0910–0432. The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078. The collections of information in 21 CFR part 814, subparts B and E, have been approved under OMB control number 0910–0231. The collections of information in 21 CFR part 820, regarding the Quality System regulation, have been approved under OMB control number 0910–0073. The collections of information in 21 CFR part 822, regarding postmarket surveillance of medical devices, have been approved under OMB control number 0910–0449.

Dated: June 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–14200 Filed 6–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on June 28, 2016, from 8 a.m. to 3:15 p.m., and June 29, 2016, from 8 a.m. to 4:15 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Lauren D. Tesh, 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, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On June 28, 2016, information will be presented to gauge investigator interest in exploring potential pediatric development plans for four products in various stages of development for adult cancer indications. The subcommittee will consider and discuss issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of these products for pediatric use. The discussion will also provide information to the Agency pertinent to the formulation of written requests for pediatric studies, if appropriate. The products under consideration are: (1) VENETOCLAX, application sponsored by AbbVie, Inc.; (2) TAZEMETOSTAT, application sponsored by Epizyme, Inc.; and (3) ATEZOLIZUMAB, application sponsored by Roche/Genentech.

On June 29, 2016, during the morning session, information will be presented to gauge investigator interest in exploring potential pediatric development plans for two products in various stages of development for adult cancer indications. The subcommittee will consider and discuss issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of these products for pediatric use. The discussion will also provide information to the Agency pertinent to the formulation of written requests for pediatric studies, if appropriate. The products under consideration are: (1) LOXO–101, application sponsored by Loxo Oncology, Inc.; and (2) ENTRECTINIB, application sponsored by Ignyta, Inc.

During the afternoon session, information will be presented on the current unmet clinical need in the nearly uniformly fatal brain tumor, diffuse intrinsic pontine glioma (DIPG), which occurs predominantly in the pediatric age group. The diagnosis of DIPG is typically based on characteristic radiographic and clinical features in lieu of brain biopsy, and histological confirmation. Recent data has demonstrated that the biology and pathophysiology of these tumors differ. There are no approved drugs for this disease. Clinical investigators seek to exploit precision medicine approaches to DIPG and use potentially predictive information from the genomic signature of tumors at either diagnosis or relapse. This information can be used to select specific molecularly targeted drugs based on the genetic aberrations of an individual patient's tumor. The Agency will seek the input of the subcommittee, including an assessment of benefit/risk given the potential for an adverse event associated with a surgical intervention in the brainstem.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views,

orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person on or before June 21, 2016. Oral presentations from the public will be scheduled between approximately 8:50 a.m. and 9:10 a.m., 11 a.m. and 11:20 a.m., 1:55 p.m. and 2:15 p.m., and 3:50 p.m. and 4:05 p.m. on June 28, 2016, and between approximately 8:50 a.m. and 9:10 a.m., 10:55 a.m. and 11:15 a.m., and 3 p.m. and 3:20 p.m. on June 29, 2016. 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 16, 2016. 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 17, 2016.

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 disabilities. If you require accommodations due to a disability, please contact Lauren D. Tesh 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.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 10, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–14212 Filed 6–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Management Grant Program; Extension of Due Dates

AGENCY: Indian Health Service, HHS.

ACTION: Notice; extension of due dates.

SUMMARY: This document extends due dates in the Fiscal Year 2016 Tribal Management Grant Program funding announcement that was published in the **Federal Register** (81 FR 20396) on April 7, 2016. Several key dates have been extended.

DATES: The Application Deadline Date, Signed Tribal Resolutions Due Date, and Proof of Non-Profit Status Due Date are all extended to June 17, 2016.

FOR FURTHER INFORMATION CONTACT: Michelle Eagle Hawk, Deputy Director, Office of Direct Service and Contracting Tribes, Indian Health Service, 5600 Fishers Lane, Mail Stop 08E17, Rockville, MD 20857, telephone (301) 443–1104. (This is not a toll-free number.)

Dated: June 9, 2016.

Elizabeth A. Fowler,

Deputy Director for Management Operations, Indian Health Service.

[FR Doc. 2016–14235 Filed 6–15–16; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Tribal Consultation and Urban Confer Sessions on the State of the Great Plains Area Indian Health Service; Correction

AGENCY: Indian Health Service (IHS), Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a document in the **Federal Register** on June 3, 2016, for the Notice of Tribal Consultation and Urban Confer Sessions on the State of the Great Plains Area Indian Health Service. The notice contained the incorrect U.S. Code regarding consultation.

FOR FURTHER INFORMATION CONTACT: CAPT Chris Buchanan, Acting Director, Great Plains Area, Indian Health Service, 115 4th Ave. SE., Suite 309, Aberdeen, South Dakota, (605) 226–7584, Fax (605) 226–7541.

Correction

In the **Federal Register** of June 3, 2016, in FR Doc. 2016–13135, on page 35787, in the first column, under the heading ''**SUPPLEMENTARY INFORMATION**: fourth paragraph,'' delete ''[42 U.S.C. 9835, Section 640(l)(4)(A)],'' and insert ''2 U.S.C. 1534.''

Dated: June 9, 2016.

Elizabeth A. Fowler,

Deputy Director for Management Operations, Indian Health Service.

[FR Doc. 2016–14232 Filed 6–15–16; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 General Medical Sciences Special Emphasis Panel.

Date: July 12, 2016.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Room 3An.12N, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Rebecca H. Johnson, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18C, Bethesda, MD 20892, 301–594–2771, *johnsonrh@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)