*marieann.brill@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. For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

**SUPPLEMENTARY INFORMATION:** *Agenda:* On September 14, 2016, the Pediatric Advisory Committee (PAC) will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act (Pub. L. 108–155). Comments about the up-coming September advisory committee meeting should be submitted to Docket No. FDA–2016–N–0567.

The PAC will meet to discuss the following products (listed by FDA Center):

1. Center for Biologics Evaluation and Research
   a. MENVEO (Meningococcal (groups A, C, Y and W–135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine)
   b. IXIARO (Japanese encephalitis vaccine)
2. Center for Drug Evaluation and Research
   a. ASACOL & ASACOL HD (mesalamine)
   b. BLOXIVERZ (neostigmine methylsulfate)
   c. DELZICOL (mesalamine)
   d. DORYX (doxycycline hyclate)
   e. KARBINAL ER (carbinoxamine maleate)
   f. KEPIVANCE (palifermin)
   g. SUSTIVA (efavirenz)
   h. TOPAMAX (topiramate)
   i. XOLAIR (omalizumab)
3. Center for Devices and Radiological Health
   a. ELANA SURGICAL KIT (HUD)
   b. BERLIN HEART EXCOR® Pediatric Ventricular Assist Device (VAD)
   c. ENTERRA™ THERAPY SYSTEM
   d. CONTEGRA PULMONARY VALVED CONDUIT
   e. PLEXIMMUNE

FDA will also provide an update of their additional ongoing analysis of a possible safety signal regarding the use of the drug product Exjade (deferasirox) in children with fever and dehydration that was discussed at the September 2015 PAC meeting.

For the products to be discussed at the PAC meeting, 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 will be 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 committee. Written submissions may be made to the contact person on or before September 7, 2016. Oral presentations from the public will be scheduled between approximately 8:30 a.m. to 9:30 a.m. 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 August 30, 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 August 31, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA is establishing a docket for public comment for the PAC meeting. The docket number is FDA–2016–N–0567. The docket will close on August 31, 2016. Comments received on or before August 31, 2016, will be provided to the committee. Comments received after the date will be taken into consideration by the Agency.

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 Marieann Brill 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).

*Additional Pediatric-focused Safety Reviews:* FDA will make available additional pediatric safety review reports for selected products at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm.* FDA is establishing a second public docket to receive input on additional pediatric-focused safety reviews that will be posted on the Internet. The docket number is FDA–2016–N–2470; the docket will open on September 12, 2016, and remain open until September 23, 2016. These safety review reports are for the following products:

1. BARACLUDE (entecavir)
2. ISENTRESS (raltegravir potassium)
3. LYSTEDA (tranexamic acid)
4. SALONPAS Pain Relief Patch (methyl salicylate 10% and l-menthol 3%).

Dated: August 11, 2016.

**Janice M. Soreth,**

*Acting Associate Commissioner, Special Medical Programs.*

[FR Doc. 2016–19589 Filed 8–16–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

### National Indian Health Outreach and Education II Program; Correction

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Indian Health Service published a document in the **Federal Register** on July 15, 2016, for the Fiscal Year 2016 National Indian Health Outreach and Education II Program. The notice contained an incorrect Announcement Number.

**FOR FURTHER INFORMATION CONTACT:** Ms. Michelle EagleHawk, Deputy Director, Office of Direct Service and Contracting Tribes, 5600 Fishers Lane, Mail Stop: 8E17, Rockville, Maryland 20857, Telephone: (301) 443–1104, email:

*Michelle.EagleHawk@ihs.gov.* (This is not a toll-free number.)

**Correction**

In the **Federal Register** of July 15, 2016, FR Doc. 2016–16819, on page 46100, in the second column at the top of the page, the correct Announcement Number should read as follows:

Announcement Number: HHS–2016–IHS–NIHOE–2–BH–HIV–AIDS–0001.

Dated: August 4, 2016.

**Elizabeth A. Fowler,**

*Deputy Director for Management Operations, Indian Health Service.*

[FR Doc. 2016–19597 Filed 8–16–16; 8:45 am]

**BILLING CODE 4165–16–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute on Aging; 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:* National Institute on Aging Special Emphasis Panel; Worm Intervention Test Data Sharing.

*Date:* September 19, 2016.

*Time:* 3:00 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Bita Nakhai, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov.*

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Worm Intervention Test One.

*Date:* September 19, 2016.

*Time:* 12:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Bita Nakhai, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov.*

*Name of Committee:* National Institute on Aging Special Emphasis Panel; NIH Phase III Clinical Trials for Alzheimer's Disease and Other Age-Related Cognitive Declines.

*Date:* October 13, 2016.

*Time:* 12:01 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Maurizio Grimaldi, MD, Ph.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Room 2C218, Bethesda, MD 20892, 301–496–9374, *grimaldim2@mail.nih.gov.*

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Alzheimer's Disease Drug Development.

*Date:* October 14, 2016.

*Time:* 12:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Alexander Parsadanian, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *parsadaniana@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS).

Dated: August 11, 2016.

**Melanie J. Gray,**

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

[FR Doc. 2016–19547 Filed 8–16–16; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Center for Advancing Translational 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 Center for Advancing Translational Sciences Special Emphasis Panel; CTSA Review.

*Date:* September 22–23, 2016.

*Time:* 8:00 a.m. to 2:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Washington DC/Rockville Hotel, Plaza 2 and 3, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Carol Lambert, Ph.D., Acting Deputy Director, Office of Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1076, Bethesda, MD 20892, 301–435–0814, *lambert@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 11, 2016.

**David Clary,**

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

[FR Doc. 2016–19542 Filed 8–16–16; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will also be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (*http://videocast.nih.gov/*).

*Name of Committee:* National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

*Date:* November 2, 2016.

*Time:* 8:00 a.m. to 4:00 p.m.

*Agenda:* Strategic Discussion of NCI's Clinical and Translational Research Programs.