availability of the draft guidance of the same title dated January 2016. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance of the same title dated January 2016 and supplements previous FDA recommendations to HCT/P establishments concerning donor testing for HBsAg and total antibody to anti-HBc, in the 2007 Donor Eligibility Guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the ''Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products.'' 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.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: August 11, 2016.

Jeremy Sharp,

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

[FR Doc. 2016–19588 Filed 8–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0567]

Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice, establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee of the Pediatric 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. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on September 14, 2016, from 8 a.m. to 5:30 p.m.

ADDRESSES: DoubleTree by Hilton Hotel Bethesda-Washington DC, 8120 Wisconsin Ave., Bethesda, MD 20814, 301–652–2000. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at *www.doubletreebethesda.com/.* You may submit your comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party many not wish to be posted, such as medical information, you or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions''.

Instructions: All submissions received must include either the Docket No. FDA–2016–N–0567 for the ''Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments''; or the Docket No. FDA–2016–N–2470 for the ''Pediatric-focused Safety Reviews'', which will be posted on the Internet, but not presented at the Pediatric Advisory Committee meeting. 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 thatyou 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.

FOR FURTHER INFORMATION CONTACT: Marieann Brill, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 240–402–3838,

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: