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.'' FDA 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 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 the 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Marieann Brill, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993–0002, 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 FDA's website at *https://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:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On September 17, 2021, the Pediatric Advisory Committee (PAC) will discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act of 2003 (Pub. L. 108–155).

The PAC will meet to discuss the following product: Center for Devices and Radiological Health FLOURISH™ Pediatric Esophageal Atresia Device (humanitarian device exemption).

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 website 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 website after the meeting. Background material is available at *https://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. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before September 10. 2021, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.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 September 2, 2021. 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 September 2, 2021.

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

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

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 (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://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: August 4, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16984 Filed 8–9–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0834]

Post-Marketing Pediatric-Focused Product Safety Reviews; 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) is establishing a public docket to collect comments related to the post-marketing pediatric-focused safety reviews of products posted between September 2, 2020, and September 2, 2021, on FDA's website but not presented at the September 17, 2021, Pediatric Advisory Committee (PAC) meeting. These reviews are intended to be available for review and comment by members of the PAC, interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public.

DATES: Submit either electronic or written comments by September 24, 2021.

ADDRESSES: FDA is establishing a docket for public comment on this document. The docket number is FDA–2021–N–0834. The docket will close on September 24, 2021. Submit either electronic or written comments by that

date. Please note that late, untimely comments will not be considered. Electronic comments must be submitted on or before September 24, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 24, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 may not wish to be posted, such as medical information, your 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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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 the Docket No. FDA–2021–N–0834 for ''Post-Marketing Pediatric-Focused Product Safety Reviews; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240–402–7500.

- 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.'' FDA 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 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 the 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, September18, 2015, or access the information at: *https://www.govinfo.gov/content/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, 240–402–7500.

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.*

SUPPLEMENTARY INFORMATION: FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA is establishing a public docket, Docket No. FDA–2021–N–0834, to receive input on post-marketing pediatric-focused safety reviews of products posted between September 2, 2020, and September 2, 2021, available on FDA's website at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm* but not presented at the September 17, 2021, PAC meeting. FDA welcomes comments by members of the PAC, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act of 2003 (Pub. L. 108–155), interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public. The docket number is FDA–2021–N–0834. The docket will open on September 3, 2021, and remain open until September 24, 2021. The post-marketing pediatric-focused safety reviews are for the following products from the following centers at FDA:

Center for Biologics Evaluation and Research

1. CUVITRU (immune globulin subcutaneous (human), 20 percent solution)
2. EPICEL (cultured epidermal autografts)
3. JIVI (antihemophilic factor (recombinant), PEGylated-aucl)
4. T.R.U.E. TEST (thin-layer rapid use epicutaneous patch test)
5. REBINYN (nonacog beta pegol (N9–GP))
6. RUBBER PANEL T.R.U.E. TEST (Rubber Panel thin-layer rapid use epicutaneous patch test)
7. ROTATEQ (Rotavirus vaccine, live, oral, pentavalent)

Center for Drug Evaluation and Research

1. APTIOM (eslicarbazepine acetate)
2. CIALIS (tadalafil)
3. COTEMPLA XR–ODT (methylphenidate extended release orally disintegrating tablets)
4. EMEND (fosaprepitant dimeglumine)
5. ENBREL (etanercept), ERELZI (etanercept-szzs), ETICOVO (etanercept-ykro)
6. FASENRA (benralizumab)
7. INTELENCE (etravirine)
8. PEGASYS (peginterferon alfa-2a)

9. TEKTURNA (aliskiren hemifumarate)
10. VIMOVO (naproxen/esomeprazole magnesium)
11. VIREAD (tenofovir disoproxil fumarate)
12. XOFLUZA (baloxavir marboxil)

Center for Devices and Radiological Health

1. CONTEGRA PULMONARY VALVED CONDUIT (Humanitarian Device Exemption (HDE))
2. ELANA SURGICAL KIT (HDE)
3. ENTERRA THERAPY SYSTEM (HDE)
4. LIPOSORBER LA–15 SYSTEM (HDE)
5. MEDTRONIC ACTIVA DYSTONIA THERAPY (HDE)
6. MINIMALLY INVASIVE DEFORMITY CORRECTION (MID–C) SYSTEM
7. PLEXIMMUNE IN–VITRO DIAGNOSTIC TEST (HDE)
8. PULSERIDER ANEURYSM NECK RECONSTRUCTION DEVICE (HDE)
9. THE TETHER—VERTEBRAL BODY TETHERING SYSTEM

Dated: August 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–17041 Filed 8–9–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Notice is hereby given of a meeting of the HEAL (Helping to End Addiction Long-Term) Multi-Disciplinary Working Group.

The meeting will be open to the public as indicated below via NIH Videocast. Individuals who 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 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 program documents and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the program documents, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: HEAL Multi-Disciplinary Working Group (MDWG) Meeting.

Date: September 1–2, 2021.

Open: September 01, 2021, 10:30 a.m. to 11:30 a.m.

Closed: September 02, 2021, 11:30 a.m. to 4:30 p.m.

Closed: September 02, 2021, 10:30 a.m. to 3:45 p.m.

Agenda: Provide an update on Helping to End Addiction Long-Term (HEAL) Initiative projects and obtain expertise from MDWG relevant to the NIH HEAL Initiative and to specific HEAL projects.

Videocast: The open portion of the meeting will be live webcast at: *https://videocast.nih.gov/.*

Place: National Institutes of Health, Building 1, Wilson Hall, 1 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rebecca G Baker, Ph.D., Office of the Director, National Institutes of Health, 1 Center Drive, Room 103A, Bethesda, MD 20892, (301) 402–1994, *Rebecca.baker@nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Office of the Director for the NIH HEAL Initiative website: *https://heal.nih.gov/news* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 5, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–17012 Filed 8–9–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Center for Scientific Review Advisory Council.

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.

URL for virtual access:—*https://videocast.nih.gov/watch=42556*

Name of Committee: Center for Scientific Review Advisory Council.

Date: September 27, 2021.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: Provide advice to the Director, Center for Scientific Review (CSR), on matters related to planning, execution, conduct, support, review, evaluation, and receipt and referral of grant applications at CSR.

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

Contact Person: Bruce Reed, Ph.D., Deputy Director, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–9159, *reedbr@mail.nih.gov*.

Information is also available on the Institute's/Center's home page: *https://public.csr.nih.gov/AboutCSR/Organization/CSRAdvisoryCouncil,* where an agenda and any additional information for the meeting will be posted when available.

(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: August 5, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–17043 Filed 8–9–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Listing of Members of the National Institutes of Health's Senior Executive Service 2021 Performance Review Board (PRB)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) announces the persons who will serve on the National Institutes of Health's Senior Executive Service 2021 Performance Review Board.

FOR FURTHER INFORMATION CONTACT: For further information about the NIH Performance Review Board, contact Mr. Kha Nguyen, Director, Division of Senior and Scientific Executive Management, Office of Human Resources, National Institutes of Health, Building 31, Room 1C31P, Bethesda, Maryland 20892, telephone 301.594.3022 (not a toll-free number), email *kha.nguyen@nih.gov.*

SUPPLEMENTARY INFORMATION: This action is being taken in accordance with