DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3941]

Advisory Committee; Digital Health Committee; Establishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of establishment.

SUMMARY: Under the Federal Advisory Committee Act, the Food and Drug Administration (FDA or Agency) is announcing the establishment of the Digital Health Advisory Committee. The Commissioner of Food and Drugs (Commissioner) has determined that it is in the public interest to establish such a committee. Duration of this committee is 2 years from the date the Charter is filed, unless the Commissioner formally determines that renewal is in the public interest.

DATES: Either electronic or written comments on the notice must be submitted by December 11, 2023. FDA is establishing a docket for public comment on this document. The docket number is FDA–2023–N–3941. The docket will close on December 11, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 11, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2023–N–3941 for ''Advisory Committee; Digital Health Committee; Establishment.'' Received comments, those filed in a timely manner, 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, 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: James Swink, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993, 301–796–6313, *James.Swink@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The Digital Health Advisory Committee (Committee) provides advice to the Commissioner or designee, on complex scientific and technical issues related to digital health technologies (DHTs). This also may include advice on the regulation of DHTs, and/or their use, including use of DHTs in clinical trials or postmarket studies subject to FDA regulation. Topics relating to DHTs, such as artificial intelligence/machine learning (AI/ML), augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring, and software, may be considered by the Committee. The Committee advises the Commissioner on issues related to DHTs, including, for example, real-world data, real-world evidence, patient-generated health data, interoperability, personalized medicine/genetics, decentralized clinical trials, use of DHTs in clinical trials for medical products, cybersecurity, DHT user experience, and Agency policies and regulations regarding these technologies. The Committee provides relevant expertise and perspective to improve Agency understanding of the benefits, risks, and clinical outcomes associated with use of DHTs. The Committee performs its duties by providing advice and recommendations on new approaches to develop and evaluate DHTs and to promote innovation of DHTs, as well as identifying risks, barriers, or unintended consequences that could result from proposed or established Agency policy or regulation for topics related to DHTs.

The Committee shall consist of a core of nine voting members including the Chair. Members and the Chair are

selected by the Commissioner or designee from among authorities knowledgeable in the fields of digital health, such as AI/ML, augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring, software development, user experience, real-world data, real-world evidence, patient-generated health data, interoperability, personalized medicine/genetics, decentralized clinical trials, cybersecurity, and implementation in clinical practice of and patient experience with digital health, as well as other relevant areas. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve either as special government employees or non-voting representatives. Federal members will serve as regular government employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who serves as an individual, but who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons.

The Commissioner or designee shall also have the authority to select from a group of individuals nominated by industry to serve temporarily as non-voting members who are identified with and represent industry interests. The number of temporary members selected for a particular meeting will depend on the meeting topic.

In announcing the establishment of this Advisory Committee under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*), FDA is also soliciting public feedback on potential topics for this committee to discuss and upon which to advise the Agency. The following topics may include, but are not limited to:

- Transparency and bias management considerations, including promoting health equity in DHTs
- Augmented reality and virtual reality technical and clinical questions
- Transparency and labeling considerations for ''opaque box'' algorithms
- Digital therapeutics
- AI/ML
- Input on regulation of AI/ML-enabled devices
- Real-world data and real-world evidence
- Patient-generated health data
- Postmarket monitoring considerations for a total product lifecycle approach to DHTs
- Interoperability
- Personalized medicine/genetics
- Wearables, remote patient monitoring, and internet of things
- Postmarket monitoring of DHTs
- Technologies to enable decentralized clinical trials
- Cybersecurity best practices in software development for cloud-based software

Elsewhere in this issue of the **Federal Register**, FDA is publishing separate documents regarding: (1) Digital Health Advisory Committee: Request for Nominations for Voting Members on a Public Advisory Committee: Digital Health Advisory Committee; (2) Request for Nomination of Individuals and Consumer Organizations for the Digital Health Advisory Committee; and (3) Request for Nomination of Individuals and Industry Organizations for the Digital Health Advisory Committee.

FDA intends to publish in the **Federal Register** a final rule adding the Digital Health Advisory Committee to 21 CFR 14.100.

Dated: October 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22566 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Commission on Childhood Vaccines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Commission on Childhood Vaccines (ACCV) will hold public meetings for the 2024 calendar year (CY). Information about ACCV, agendas, and materials for these meetings can be found on the ACCV website at *https://www.hrsa.gov/advisory-committees/vaccines/index.html.*

DATES: ACCV meetings will be held on March 7, 2024, 10:00 a.m.–4:00 p.m. Eastern Time (ET); March 8, 2024, 10:00 a.m.–4:00 p.m. ET; September 5, 2024, 10:00 a.m.–4:00 p.m. ET; September 6, 2024, 10:00 a.m.–4:00 p.m. ET.

ADDRESSES: Meetings may be held in-person or by Zoom webinar. For updates on how the meeting will be held, visit the ACCV website meeting page included below 30 business days before the date of the meeting, where instructions for joining meetings either in-person or remotely will be posted. In-person ACCV meetings will be held at 5600 Fishers Lane, Rockville, MD 20857. For meeting information updates, go to the ACCV website meeting page at *https://www.hrsa.gov/advisory-committees/vaccines/meetings.html.*

FOR FURTHER INFORMATION CONTACT: Pita Gomez, Principal Staff Liaison, Division of Injury Compensation Programs, HRSA, 5600 Fishers Lane, 8W–25A, Rockville, MD 20857; 800–338–2382; or *ACCV@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACCV provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other issues related to implementation of the National Vaccine Injury Compensation Program and concerning other matters as described under section 2119 of the Public Health Service Act (42 U.S.C. 300aa–19).

Since priorities dictate meeting times, be advised that start times, end times, and agenda items are subject to change. For CY 2024 meetings, agenda items may include, but are not limited to: updates from the Division of Injury Compensation Programs, Department of Justice, Office of Infectious Disease and HIV/AIDS Policy (HHS), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health) and Center for Biologics Evaluation and Research (Food and Drug Administration). Refer to the ACCV website listed above for all current and updated information concerning the CY 2024 ACCV meetings, including draft agendas and meeting materials that will be posted 5 calendar days before the meeting.

These meetings are open to the public. Meetings held by Zoom webinar will require registration. Registration details will be provided on our ACCV website at *https://www.hrsa.gov/advisory-committees/vaccines/meetings.html.* All registrants will be asked to provide their name, affiliation, and email address. After registration, individuals will receive personalized Zoom information via email.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting(s). Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to ACCV should