subset of study participants to monitor the quality of data collection interviews and to validate that the interviewer spoke with the participant; (4) Implementation study interviews: using topic guides, collect information from program supervisors and frontline staff, community providers, child welfare staff, and parents enrolled in the programs to assess the fidelity of implementation, document program services, and gather operational lessons; and (5) Parent Interview Information Form: demographic information to support analysis of parent perspectives by personal characteristics and history. Future information collection requests will be submitted to collect follow-up data.

Respondents: Parents enrolled in the R3-Impact Study, and program and agency staff involved in implementing the R3 interventions.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Baseline Parent Survey	2,750	1	.75	2063	688
Contact Form	1,843	4	.17	1,253	418
Validation Interviews	275	1	.08	22	7
Topic Guide–Child Welfare Lead Staff.	60	1	1	60	20
Topic Guide–Child Welfare Frontline Staff.	60	1	1	60	20
Topic Guide–Partners	120	1	1	120	40
Topic Guide–Program Managers	60	1	1.5	90	30
Topic Guide–Mentor Supervisors	60	1	1.5	90	30
Topic Guide–Parent/Family Mentors	60	1	1.5	90	30
Topic Guide–Parents	30	1	1	30	10
Parent Interview Information Form	30	1	.1	3	1

Estimated Total Annual Burden Hours: 1,294.

Authority: The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act; Pub. L. 115–271)

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–17364 Filed 8–11–23; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2483]

Microbiology Devices Panel of the Medical Devices 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 meeting of the Microbiology Devices Panel of the Medical Devices Advisory Committee (the Committee). The general function of the Committee as a medical device panel is to provide advice and recommendations to FDA. In addition, the Committee will meet to discuss and provide advice to FDA on in vitro diagnostic devices used in pandemic preparedness and response to satisfy, in part, a requirement under the Food and Drug Omnibus Reform Act of 2022 (FDORA). 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 virtually on September 7, 2023, from 9 a.m. to 5:15 p.m. Eastern Time and September 8, 2023, from 9:30 a.m. to 3:45 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2023–N–2483. Please note that late, untimely filed comments will not be considered. The docket will close on October 10, 2023. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 10, 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.

Comments received on or before August 30, 2023, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

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–2023–N–2483 for ''Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; 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: Candace Nalls, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993–0002, 301–636–0510, *Candace.Nalls@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 the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: All meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. FDA is seeking the Committee's preliminary input on potential future reclassification of certain microbiology devices to inform FDA's thinking regarding whether reclassification from class III to class II may be appropriate for such devices. Specifically, on September 7, 2023, during session I, the Committee will discuss and make recommendations regarding a potential future reclassification from class III to class II with special controls of nucleic acid and serology-based in vitro diagnostic devices indicated for use to aid in diagnosis of hepatitis B virus (HBV) infection and/or for use to aid in the management of HBV infected patients. The Committee, during session II, will discuss and make recommendations regarding a potential future reclassification from class III to class II with special controls of serology-based in vitro diagnostic devices indicated for use to aid in the detection of past, recent, or current infection with human parvovirus B19. The Committee, during session III, will discuss and make recommendations regarding a potential future reclassification from class III to class II with special controls of cell-mediated immune reactivity in vitro diagnostic devices indicated for use to aid in identification of in vitro responses to peptide antigens that are associated with *Mycobacterium tuberculosis* infection and/or for use as detection of effector T cells that respond to stimulation by *M. tuberculosis* agents.

All devices to be discussed by the Committee on September 7, 2023, are postamendments devices that currently are classified into class III under section 513(f)(1) of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 360c(f)(1)). For these devices, the Committee will discuss: (1) if there is sufficient information for FDA to consider reclassifying them from class III to class II and (2) what special controls, in addition to general controls, may be appropriate and necessary to provide reasonable assurance of safety and effectiveness for these devices, if FDA were to take action to reclassify them into class II devices. FDA intends to follow the procedures outlined in section 513 of the FD&C Act related to the reclassification of postamendments devices after considering the Committee's input.

On September 8, 2023, the Committee will discuss and provide recommendations to FDA regarding topics related to in vitro diagnostic devices used in pandemic preparedness and response, consistent with the requirements under section 3302 of FDORA.

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 on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely

resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before August 18, 2023, will be provided to the Committee. Oral presentations from the public will be scheduled on September 7, 2023, between approximately 10:05 a.m. and 10:35 a.m., 1:15 p.m. and 1:45 p.m., and 3:30 p.m. and 4 p.m. Eastern Time; and on September 8, 2023, between approximately 10:30 a.m. and 11:30 a.m. Eastern Time. 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 10, 2023. 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 11, 2023.

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 Artair Mallett, at *Artair.Mallett@fda.hhs.gov* or 301–796–9638 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. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. No participant will be prejudiced by this waiver, and that the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: August 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17287 Filed 8–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), Office of Strategic Partnerships and Technology Innovation (OST) has modified its organizational structure.

DATES: These new organizations' structures were approved by the Secretary of Health and Human Services on June 27, 2023, and effective on August 8, 2023.

FOR FURTHER INFORMATION CONTACT: Denise Huttenlocker, Associate Director for Management, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–743–1760.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is amended to reflect Food and Drug Administration's reorganization of CDRH, OST.

This reorganization changed the OST organizational structure from an office with three divisions to an office with five suboffices each with their own divisions. The previous divisions were: the Division of All Hazards Response, Science and Strategic Partnerships, the Division of Digital Health, and the Division of Technology and Data Services. The OST will elevate the programs performed by these former divisions to a super office structure whereby these divisions are abolished, and their functions and resources are realigned across five new OST suboffices. DCCC. ORGANIZATION. The Office of Office of Strategic Partnerships and Technology Innovation is headed by the Director of Strategic Partnerships and Technology Innovation and includes the following organizational units:

Office of Readiness and Response

Division of All Hazards Preparedness and Response
Division of Standards and Conformity Assessment
Division of Medical Device Cybersecurity

Office of Equity and Innovative Development

Division of Patient-Centered Development
Division of Heath Equity
Division of Partnerships and Innovation

Digital Health Center of Excellence

Division of Digital Health Policy
Division of Digital Health Technology Assessment
Division of Digital Health Outreach

Office of Technology and Data Services

Division of Business Transformation Delivery
Division of Technology Services
Division of Data Services

Office of Supply Chain Resilience

Division of Prevention, Innovation, and Resilience
Division of Shortage Assessment and Product Authentication

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the