To pay the ANDA, DMF, API facility, FDF facility, CMO facility, and GDUFA program fees, a Generic Drug User Fee Cover Sheet must be completed, available at *https://www.fda.gov/gdufa and https://userfees.fda.gov/OA_HTML/gdufaCAcdLogin.jsp,* and a user fee identification (ID) number must be generated. Payment must be made in U.S. currency drawn on a U.S. bank by electronic check, check, bank draft, U.S. postal money order, credit card, or wire transfer. The preferred payment method is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov,* a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the Generic Drug User Fee Cover Sheet and generating the user fee ID number.

Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* (Note: only full payments are accepted; no partial payments can be made online.) Once an invoice is located, ''Pay Now'' should be selected to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

The user fee ID number must be included on the check, bank draft, or postal money order and must be made payable to the order of the Food and Drug Administration. Payments can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If checks are to be sent by a courier that requests a street address, the courier can deliver checks to U.S. Bank, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. For questions concerning courier delivery, U.S. Bank can be contacted at 314–418–4013. This telephone number is only for questions about courier delivery.) The FDA post office box number (P.O. Box 979108) must be written on the check, bank draft, or postal money order.

For payments made by wire transfer, the unique user fee ID number must be referenced. Without the unique user fee ID number, the payment may not be applied. If the payment amount is not applied, the invoice amount will be referred to collections. The originating financial institution may charge a wire transfer fee. Applicable wire transfer fees must be included with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53–0196965.

Dated: October 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22099 Filed 10–6–22; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2274]

Medical Devices; Voluntary Total Product Life Cycle Advisory Program Pilot

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration's (FDA, Agency, or we) Center for Devices and Radiological Health (CDRH or Center) is announcing its voluntary Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot that will begin in fiscal year (FY) 2023 with the initial phase, hereafter referred to as the TAP Pilot Soft Launch. The TAP Pilot is one of the commitments agreed to between FDA and industry as part of the reauthorization of the Medical Device User Fee Amendments for FY 2023 through FY 2027 (MDUFA V). The long-term vision for TAP is to help spur more rapid development and more rapid and widespread patient access to safe, effective, high-quality medical devices of public health importance. Over the course of MDUFA V, the voluntary TAP Pilot is intended to demonstrate the feasibility and benefits of process improvements to FDA's early interactions with participants and of FDA's facilitation of interactions between participants and stakeholders that support the vision for TAP.

DATES: Beginning January 1, 2023, FDA is seeking requests for enrollment in the TAP Pilot Soft Launch for FY 2023. Either electronic or written comments on this notice must be submitted by January 10, 2023 to ensure that the Agency considers your comment on this notice before it begins work on the next phase of the TAP Pilot.

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 January 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.

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–2022–N–2274 for ''Medical Devices; Voluntary Total Product Life Cycle

Advisory Program Pilot.'' 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 office 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.'' 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *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: Matthew Hillebrenner, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2302, Silver Spring MD 20993, 301–796–6358, *matthew.hillebrenner@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

As part of the reauthorization of the MDUFA V,[1] FDA committed to establish the TAP Pilot during the course of MDUFA V.[2] The long-term vision for TAP is to help spur more rapid development and more rapid and widespread patient access to safe, effective, high-quality medical devices of public health importance. A mature TAP is also intended to help ensure the sustained success of the Breakthrough Devices program (see more information on this program below in Section I.C). Through the TAP Pilot, as described in the MDUFA V commitment letter, FDA will provide the following types of strategic engagement for innovative devices of public health importance:

• Improving participants' experiences with FDA by providing for more timely premarket interactions;

• Enhancing the experience of all participants throughout the device development and review process, including FDA staff;

• Facilitating improved strategic decision-making during device development, including earlier identification, assessment, and mitigation of device development risk;

• Facilitating regular, solutions-focused engagement between FDA review teams, participants, and other stakeholders, such as patients, providers, and payers, beginning early in device development; and

• Collaborating to better align expectations regarding evidence generation, improve submission quality, and improve the efficiency of the premarket review process (Ref. 1).[3]

Consistent with the MDUFA V commitment letter, FDA initially intends to include only devices with a granted Breakthrough designation in the TAP Pilot in FY 2023–FY 2025 and intends to include devices with a granted Breakthrough designation or request for inclusion in the Safer Technologies Program (STeP) in FY 2026–FY 2027. At this time, devices regulated by the Center for Biologics Evaluation and Research (CBER) are outside the scope of the TAP Pilot.[4] In addition, given the complexities involved with the review of combination products,[5] including coordination with review staff outside of CDRH, we anticipate that it will be difficult for sponsors of combination products to benefit fully from the TAP Pilot. Therefore, at this time, we do not intend to enroll combination products in the Pilot.

A. Enrollment and Pilot Expansion Schedule

To implement the TAP Pilot and in accordance with the MDUFA V commitment letter, FDA intends to take a phased-enrollment approach throughout the duration of MDUFA V. The first phase is the TAP Pilot Soft Launch, which will be conducted during FY 2023 (Ref. 1). During the TAP Pilot Soft Launch phase, FDA intends to enroll up to 15 devices in the Office of Health Technology 2 (OHT2): Office of Cardiovascular Devices. Selection of OHT2 for the TAP Pilot Soft Launch was based on consideration of multiple factors, including OHT2's historical number of granted Breakthrough designations, workload, staffing levels, and expertise, as well as experience with review paradigms involving rapid interactions, such as Early Feasibility Studies. For example, OHT2 has granted 163 Breakthrough Device designations as of June 30, 2022, which represents 23.7 percent of the 687 Breakthrough Device designations granted by CDRH.

In subsequent fiscal years, FDA intends to expand the TAP Pilot to enroll more devices and to include devices reviewed in other OHTs.[6] Specifically, as stated in the MDUFA V commitment letter, in FY 2024, the TAP Pilot will continue to support devices enrolled in the previous fiscal year and will expand to enroll up to 45 additional devices in at least two OHTs (*i.e.,* up to 60 total devices enrolled through FY 2024). In FY 2025, the TAP Pilot will continue to support devices enrolled in previous fiscal years and will expand to enroll up to 65 additional devices in at least four OHTs (*i.e.,* up to 125 total devices enrolled through FY 2025). In FY 2026 and FY 2027, the TAP Pilot will continue to support devices enrolled in previous

[1] MDUFA V spans from FY 2023 through FY 2027. The fiscal year runs from October 1 through September 30, so FY 2023 runs from October 1, 2022 through September 30, 2023.

[2] For more information on FDA's TAP Pilot, see the TAP Pilot web page at: *https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap.*

[3] For more information on the goals and objectives of the TAP Pilot, see the MDUFA V commitment letter, MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027, available at *https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v.*

[4] In the MDUFA V commitment letter, FDA committed to conducting the TAP Pilot within Offices of Health Technology (OHTs), which are offices that review devices regulated by CDRH.

[5] See 21 CFR 3.2(e).

[6] During the TAP Pilot, if spaces remain available in participating OHTs for any fiscal year, or if resources permit, FDA may consider enrolling devices from OHTs not yet participating in the TAP Pilot.

fiscal years and will expand to enroll up to 100 additional devices each fiscal year within existing OHTs or expand to additional OHTs, depending on lessons learned from the FY 2023 to FY 2025 experience (*i.e.,* up to 225 total devices enrolled through FY 2026 and up to 325 total devices enrolled through FY 2027). For FY 2024–FY 2027, selection of the OHTs will include consideration of the factors mentioned above regarding the selection of OHT2 for the Soft Launch, experience from prior years, and input from industry and other stakeholders (Ref. 1). For FY 2024–FY 2027, FDA plans to announce the OHT(s) selected for future participation in the TAP Pilot via the TAP Pilot web page no later than 30 days prior to the start of each fiscal year.

B. Enrollment in the TAP Pilot

FDA will inform potential participants of the TAP Pilot as part of the Breakthrough designation process or request for inclusion in the STeP process, as applicable. Eligible TAP Pilot participants will be enrolled on a first-come, first-served basis. The Pilot's capacity for additional participating devices and the number of participating OHTs within CDRH will increase each fiscal year as described in Section I.A. As noted above, at this time, devices regulated by CBER are outside the scope of the TAP Pilot, and we do not intend to enroll combination products in the Pilot.

FDA intends to enroll devices reviewed in a participating OHT in the voluntary TAP Pilot using the following enrollment criteria, consistent with the MDUFA V commitment letter:

1. Devices will be those with either a granted Breakthrough designation or (during FY 2026 and FY 2027) a granted request for inclusion in the Safer Technologies Program (STeP);
2. Potential participants will not have submitted a Pre-Submission about the device after being granted a Breakthrough designation or inclusion in STeP;
3. Devices will be early in their device development process (*e.g.,* have not yet initiated a pivotal study for the device) at time of enrollment; and
4. Each potential participant will have a maximum of one device enrolled in the TAP Pilot per fiscal year.

Enrollment in the TAP Pilot, including in the Soft Launch, does not change any statutory or regulatory requirements that may apply to the TAP Pilot device or participant, including, but not limited to, investigational device exemption (IDE) requirements under 21 CFR part 812; premarket notification requirements under 21 CFR part 807, subpart E; premarket approval requirements under 21 CFR part 814; and/or De Novo classification requirements under 21 CFR part 860, subpart D. It is the sponsor's responsibility to ensure compliance with applicable laws and regulations.

C. Procedures for Enrollment in the TAP Pilot

To have a device considered for enrollment in the voluntary TAP Pilot, sponsors should submit an amendment to the Q-submission under which their device was granted Breakthrough designation or (during FY 2026 and FY 2027) inclusion in STeP, with the following information:

1. A subject heading clearly indicating ''TAP Pilot Request for Enrollment'';
2. Name and address of the device sponsor; and
3. The Q-Submission number under which the device proposed for enrollment in the TAP Pilot was granted Breakthrough designation or inclusion in STeP.

For more information on the Breakthrough Devices program, see FDA's website, *https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program,* and FDA Guidance, Breakthrough Devices Program (Ref. 2). For more information on STeP, see FDA's website, *https://www.fda.gov/medical-devices/how-study-and-market-your-device/safer-technologies-program-step-medical-devices* and FDA Guidance, Safer Technologies Program for Medical Devices (Ref. 3).

Following receipt of a request for enrollment in the TAP Pilot, FDA intends to consider the request using the enrollment criteria outlined in Section I.B if spaces remain available in the TAP Pilot for the relevant fiscal year. Within 30 days of receipt, FDA intends to notify the potential participant in writing whether or not the device has been enrolled into the TAP Pilot. If a participant's device is enrolled into the TAP Pilot, FDA will contact the participant to schedule an initial meeting to provide an overview of the TAP Pilot processes, expectations, and engagement opportunities. If, after review of a request for enrollment, a device is not enrolled in the TAP Pilot, FDA will identify the reason(s) for that decision.

As noted in Section I.B., eligible TAP Pilot participants will be enrolled on a first-come, first-served basis, for which we plan to use the date of receipt of requests for enrollment in each respective fiscal year. To facilitate an orderly enrollment process, FDA does not intend to consider requests to enroll in the TAP Pilot until the start of the fiscal year in which the participant wishes to enroll. (For example, beginning on October 1, 2023, FDA intends to consider requests to enroll in the TAP Pilot for FY 2024.) If the maximum number of devices has been enrolled for the fiscal year in which a request is received, FDA intends to notify the sponsor submitting the request that enrollment in the TAP Pilot has reached capacity for the current fiscal year. FDA also intends to provide enrollment updates, including a notification that we have reached capacity for a given fiscal year, on the TAP Pilot web page.[7]

D. Performance Metrics

In an effort to achieve the TAP Pilot objectives, FDA committed to implement and track the following quantitative performance metrics[8] beginning in FY 2024:

- CDRH will engage in a teleconference with the participant on requested topic(s) pertaining to the TAP device within 14 days of the request for 90 percent of requests for interaction.
- CDRH will provide written feedback on requested biocompatibility and sterility topics(s) pertaining to the TAP device within 21 days of the request for 90 percent of such requests for written feedback.
- CDRH will provide written feedback on requested topic(s) pertaining to the TAP device other than biocompatibility and sterility within 40 days of the request for 90 percent of requests for written feedback.

During this voluntary TAP Pilot, CDRH staff intend to be available to answer questions or address concerns that may arise. The TAP Pilot Program participants may comment on and discuss their experiences with the Center.

For informational purposes, FDA will conduct an assessment of the TAP Pilot using an independent third party (or parties) to assess the TAP Pilot. This assessment will include a participant survey and quantitative and qualitative success metrics, starting in FY 2024, that include, but are not limited to: (a) the extent to which FDA is successful at meeting the quantitative goals described above; (b) participant satisfaction with

[7] For more information on FDA's TAP Pilot, see the TAP Pilot web page at: *https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap.*

[8] See section J.3 of the MDUFA V commitment letter, MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027, available at: *https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v.*

the timeliness, frequency, quality, and efficiency of interactions with and written feedback from FDA; (c) participant satisfaction with the timeliness, frequency, quality, and efficiency of voluntary interactions with non-FDA stakeholders facilitated by FDA (if utilized); and (d) an overall assessment of the outcomes of the Pilot and opportunities for improvement (Ref. 1).

II. Request for Comments

FDA understands that to make this program the most effective, we will need additional feedback and suggestions from industry and other stakeholders. FDA encourages all stakeholders to comment on the TAP Pilot generally. The Agency is particularly interested in feedback on the following topics:

1. TAP Pilot participation will expand to include additional Offices of Health Technology (OHTs) in FY 2024 through FY 2027. In what order do you believe additional OHTs should be included in the TAP Pilot? Please provide the reasons/rationale/justification to support your recommendations in your response.

2. The TAP Pilot is intended to facilitate improved strategic decision-making and better align expectations regarding evidence generation during device development, including through facilitating interactions between TAP participants and stakeholders, such as patients, providers, and payers. These interactions are voluntary and may, for example, help provide a better understanding of the current treatment options used to treat or manage a given condition, which outcomes are most important to patients and providers, how a new technology may fit into clinical care paradigms and patient lives, how patients and providers consider tradeoffs between anticipated benefits and risks, and the evidence that may help support clinical adoption and coverage.

(1) What additional questions or topics could patients, providers, and/or payers address that could help inform sponsors' strategic decision-making?

(2) Are there specific patient, provider, or payer organizations whose members may be well-suited and willing to provide insights regarding evidence generation strategies to sponsors who wish to obtain such input?

III. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information regarding Q-Submissions have been approved under OMB control number 0910–0756.

IV. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. U.S. Food and Drug Administration, ''MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027,'' available at *https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v.*
2. U.S. Food and Drug Administration, ''Breakthrough Devices Program,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program.*
3. U.S. Food and Drug Administration, ''Safer Technologies Program for Medical Devices,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safer-technologies-program-medical-devices.*
4. U.S. Food and Drug Administration, ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.*
5. U.S. Food and Drug Administration, ''Total Product Life Cycle Advisory Program (TAP),'' available at *https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap/.*

Dated: October 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21835 Filed 10–11–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; 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 National Advisory Child Health and Human Development Council Stillbirth Working Group.

The meeting will be open to the public as indicated below. 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 session will be videocast and can be accessed from the NIH Videocasting website (*http://videocast.nih.gov/*).

Name of Committee: National Advisory Child Health and Human Development Council; Stillbirth Working Group.

Date: October 20, 2022.

Time: 1:30 p.m. to 5 p.m.

Agenda: The NICHD Stillbirth Working Group of Council (Working Group) is charged with providing a report to the National Advisory Child Health and Human Development Council focusing on the current barriers to collecting data on stillbirths throughout the United States, communities at higher risk of stillbirth, the psychological impact and treatment for mothers following stillbirth, and known risk factors for stillbirth.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892–7510 (Virtual Meeting).

Contact Person: Dr. Natasha H. Williams, Branch Chief, Office of Legislation and Public Policy, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, *natasha.williams2@nih.gov*, Bethesda, MD 20892–7510, (240) 551–4985.

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 Institute's/Center's home page: *https://www.nichd.nih.gov/about/advisory,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS.)

Dated: October 5, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–22068 Filed 10–11–22; 8:45 am]

BILLING CODE 4140–01–P