Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by December 12, 2022.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10628—Initial Request for State Implemented Moratorium Form

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Initial Request for State Implemented Moratorium Form; *Use:* Congress has enacted section 1866 (j)(7) of the Social Security Act, which allows for the imposition of temporary moratorium. CMS promulgated 42 CFR 424.570 in order to comply with that statute, which requires that prior to implementing state Medicaid moratoria the state Medicaid agency must notify the Secretary in writing, including all of the details of the moratoria, and obtain the Secretary's concurrence with the imposition of the moratoria.

The Initial Request for State Medicaid Implemented Moratorium, named the ''Initial Request for State Medicaid Implemented Moratorium'' has been created to collect that data, in a uniform manner, which the states report to CMS when they request a moratorium. Currently, CMS is collecting this data on an ad-hoc basis, however this process needs to be standardized so that moratoria decisions are being made based on the same criteria each time. The form may be used by states and territories who wish to impose a Medicaid or Children's Health Insurance Program moratorium. CMS will use this information as a standardized method to collect and track state-imposed moratoria requests.

Form number: CMS–10628 (OMB control number: 0938–1328); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 5; *Number of Responses:* 5; *Total Burden Hours:* 25. (For questions regarding this collection contact Alisha Jacobs at 410–786–0671).

Dated: October 5, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–22077 Filed 10–11–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration.

[Docket No. FDA–2022–N–2354]

Generic Drug User Fee Rates for Fiscal Year 2023

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (FD&C Act or statute), as amended by the Generic Drug User Fee Amendments of 2022 (GDUFA III), authorizes the Food and Drug Administration (FDA, Agency, or we) to assess and collect fees for abbreviated new drug applications (ANDAs); drug master files (DMFs); generic drug active pharmaceutical ingredient (API) facilities, finished dosage form (FDF) facilities, and contract manufacturing organization (CMO) facilities; and generic drug applicant program user fees. In this document, FDA is announcing fiscal year (FY) 2023 rates for GDUFA III fees. These fees are effective on October 1, 2022, and will remain in effect through September 30, 2023.

FOR FURTHER INFORMATION CONTACT: Robert Marcarelli, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, and the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov,* 301–796–7223.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744A and 744B of the FD&C Act (21 U.S.C. 379j–41 and 379j–42), as amended by GDUFA III, authorize FDA to assess and collect fees associated with human generic drug products. Fees are assessed on: (1) certain types of applications for human generic drug products; (2) certain facilities where APIs and FDFs are produced; (3) certain

DMFs associated with human generic drug products; and (4) generic drug applicants who have ANDAs (the program fee) (see section 744B(a)(2) through (5) of the FD&C Act). For more information about GDUFA III, please refer to the FDA website (*https://www.fda.gov/gdufa*).

For FY 2023, the generic drug fee rates are: ANDA ($240,582), DMF ($78,293), domestic API facility ($37,544), foreign API facility ($52,544), domestic FDF facility ($213,134), foreign FDF facility ($228,134), domestic CMO facility ($51,152), foreign CMO facility ($66,152), large size operation generic drug applicant program ($1,620,556), medium size operation generic drug applicant program ($648,222), and small business generic drug applicant program ($162,056). These fees are effective on October 1, 2022, and will remain in effect through September 30, 2023. The fee rates for FY 2023 are set out in table 1.

TABLE 1—FEE SCHEDULE FOR FY 2023

Generic drug fee category	Fees rates for FY 2023
Applications	
Abbreviated New Drug Application (ANDA)	$240,582
Drug Master File (DMF)	78,293
Facilities	
Active Pharmaceutical Ingredient (API)—Domestic	37,544
API—Foreign	52,544
Finished Dosage Form (FDF)—Domestic	213,134
FDF—Foreign	228,134
Contract Manufacturing Organization (CMO)—	51,152
Domestic	
CMO—Foreign	66,152
GDUFA Program	
Large size operation generic drug applicant	1,620,556
Medium size operation generic drug applicant	648,222
Small business operation generic drug applicant	162,056

II. Fee Revenue Amount for FY 2023

The fee revenue amount for FY 2023 for GDUFA III is $582,500,000. Since this is the first fiscal year of the GDUFA III authorization period, there is no inflation adjustment. Applicable inflation adjustments shall be made beginning with FY 2024.

Beginning with FY 2024, FDA shall, in addition to the inflation adjustment, apply the capacity planning adjustment under section 744B(c)(2) of the FD&C Act to further adjust, as needed, the fee revenue and fees to reflect changes in the resource capacity needs of FDA for human generic drug activities.

Beginning with FY 2024, FDA may, in addition to the inflation and capacity planning Adjustments, apply the operating reserve adjustment under section 744B(c)(3) of the FD&C Act to further increase the fee revenue and fees if necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in such section (or as applicable, shall apply such adjustment to decrease the fee revenues and fees to provide for not more than 12 weeks of such operating reserves).

III. Fee Amounts for FY 2023

GDUFA III directs FDA to use the annual revenue amount determined under the statute as a starting point to set the fee rates for each fee type. The fee revenue amount for FY 2023 is $582,500,000. The ANDA, DMF, API facility, FDF facility, CMO facility, and generic drug applicant program fee (GDUFA program fee) calculations for FY 2023 are described in this document.

A. ANDA Filing Fee

Under GDUFA III, the FY 2023 ANDA filing fee is owed by each applicant that submits an ANDA on or after October 1, 2022. This fee is due on the submission date of the ANDA. Section 744B(b)(2)(B) of the FD&C Act specifies that the ANDA fee will make up 33 percent of the $582,500,000, which is $192,225,000.

To calculate the ANDA fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2023. The submissions are broken down into three categories: new originals (submissions that have not been received by FDA previously); submissions that FDA refused to receive (RTR) for reasons other than failure to pay fees; and applications that are resubmitted after an RTR decision for reasons other than failure to pay fees. An ANDA counts as one FAE; however, 75 percent of the fee paid for an ANDA that has been RTR shall be refunded according to GDUFA III if: (1) the ANDA is refused for a cause other than failure to pay fees or (2) the ANDA has been withdrawn prior to receipt (section 744B(a)(3)(D)(i) of the FD&C Act). Therefore, an ANDA that is considered not to have been received by FDA due to reasons other than failure to pay fees or withdrawn prior to receipt counts as one-fourth of an FAE. After an ANDA has been RTR, the applicant has the option of resubmitting. For user fee purposes, these resubmissions are equivalent to new original submissions: ANDA resubmissions are charged the full amount for an application (one FAE).

FDA utilized data from ANDAs submitted from October 1, 2020, to April 30, 2022, to estimate the number of new original ANDAs that will incur filing fees in FY 2023. For FY 2023, FDA estimates that approximately 800 new original ANDAs will be submitted and incur filing fees. Not all of the new original ANDAs will be received by FDA and some of those not received will be resubmitted in the same fiscal year. Therefore, FDA expects that the FAE count for ANDAs will be 799 for FY 2023.

The FY 2023 application fee is estimated by dividing the number of FAEs that will pay the fee in FY 2023 (799) into the fee revenue amount to be derived from ANDA application fees in FY 2023 ($192,225,000). The result, rounded to the nearest dollar, is a fee of $240,582 per ANDA.

The statute provides that those ANDAs that include information about the production of APIs other than by reference to a DMF will pay an additional fee that is based on the number of such APIs and the number of

facilities proposed to produce those ingredients (see section 744B(a)(3)(F) of the FD&C Act). FDA anticipates that this additional fee is unlikely to be assessed often; therefore, FDA has not included projections concerning the amount of this fee in calculating the fees for ANDAs.

B. DMF Fee

Under GDUFA III, the DMF fee is owed by each person that owns a type II API DMF that is referenced, on or after October 1, 2012, in a generic drug submission by an initial letter of authorization. This is a one-time fee for each DMF. This fee is due on the earlier of the date on which the first generic drug submission is submitted that references the associated DMF or the date on which the DMF holder requests the initial completeness assessment. Under section 744B(a)(2)(D)(iii) of the FD&C Act, if a DMF has successfully undergone an initial completeness assessment and the fee is paid, the DMF will be placed on a publicly available list documenting DMFs available for reference.

To calculate the DMF fee, FDA assessed the volume of DMF submissions over time. We assessed DMFs from October 1, 2020, to April 30, 2022, and concluded that averaging the number of fee-paying DMFs provided the most accurate model for predicting fee-paying DMFs for FY 2023. The monthly average of paid DMF submissions FDA received in FY 2021 and FY 2022 is 31. To determine the FY 2023 projected number of fee-paying DMFs, the average of 31 DMF submissions is multiplied by 12 months, which results in 372 estimated FY 2023 fee-paying DMFs. FDA is estimating 372 fee-paying DMFs for FY 2023.

The FY 2023 DMF fee is determined by dividing the DMF target revenue by the estimated number of fee-paying DMFs in FY 2023. Section 744B(b)(2)(A) of the FD&C Act specifies that the DMF fees will make up 5 percent of the $582,500,000, which is $29,125,000. Dividing the DMF revenue amount ($29,125,000) by the estimated fee-paying DMFs (372), and rounding to the nearest dollar, yields a DMF fee of $78,293 for FY 2023.

C. Foreign Facility Fee Differential

Under GDUFA III, the fee for a facility located outside the United States and its territories and possessions shall be $15,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions. The basis for this differential is the extra cost incurred by conducting an inspection outside the United States and its territories and possessions.

D. FDF and CMO Facility Fees

Under GDUFA III, the annual FDF facility fee is owed by each person who owns an FDF facility that is identified in at least one approved generic drug submission owned by that person or its affiliates. The CMO facility fee is owed by each person who owns an FDF facility that is identified in at least one approved ANDA but is not identified in an approved ANDA held by the owner of that facility or its affiliates. Section 744B(b)(2)(C) of the FD&C Act specifies that the FDF and CMO facility fee revenue will make up 20 percent of the $582,500,000, which is $116,500,000.

To calculate the fees, data from FDA's Integrity Services (IS) were utilized as the primary source of facility information for determining the denominators of each facility fee type. IS is the master data steward for all facility information provided in generic drug submissions received by FDA. A facility's reference status in an approved generic drug submission is extracted directly from submission data rather than relying on data from self-identification. This information provided the number of facilities referenced as FDF manufacturers in at least one approved generic drug submission. Based on FDA's IS data, the FDF and CMO facility denominators are 176 FDF domestic, 293 FDF foreign, 90 CMO domestic, and 114 CMO foreign facilities for FY 2023.

GDUFA III specifies that the CMO facility fee is to be equal to 24 percent of the FDF facility fee. Therefore, to generate the target collection revenue amount from FDF and CMO facility fees ($116,500,000), FDA must weight a CMO facility as 24 percent of an FDF facility. FDA set fees based on the estimate of 176 FDF domestic, 293 FDF foreign, 21.60 CMO domestic (90 multiplied by 24 percent), and 27.36 CMO foreign facilities (114 multiplied by 24 percent), which equals 518 total weighted FDF and CMO facilities for FY 2023.

To calculate the fee for domestic facilities, FDA first determines the total fee revenue that will result from the foreign facility differential by subtracting the fee revenue resulting from the foreign facility fee differential from the target collection revenue amount ($116,500,000) as follows: the foreign facility fee differential revenue equals the foreign facility fee differential ($15,000) multiplied by the number of FDF foreign facilities (293) plus the foreign facility fee differential ($15,000) multiplied by the number of CMO foreign facilities (114), totaling $6,105,000. This results in foreign fee differential revenue of $6,105,000 from the total FDF and CMO facility fee target collection revenue.

Subtracting the foreign facility differential fee revenue ($6,105,000) from the total FDF and CMO facility target collection revenue ($116,500,000) results in a remaining facility fee revenue balance of $110,395,000. To determine the domestic FDF facility fee, FDA divides the $110,395,000 by the total weighted number of FDF and CMO facilities (518), which results in a domestic FDF facility fee of $213,134. The foreign FDF facility fee is $15,000 more than the domestic FDF facility fee, or $228,134.

According to GDUFA III, the domestic CMO fee is calculated as 24 percent of the amount of the domestic FDF facility fee. Therefore, the domestic CMO fee is $51,152, rounded to the nearest dollar. The foreign CMO fee is calculated as the domestic CMO fee plus the foreign fee differential of $15,000. Therefore, the foreign CMO fee is $66,152.

E. API Facility Fee

Under GDUFA III, the annual API facility fee is owed by each person who owns a facility that is identified in: at least one approved generic drug submission or a Type II API DMF referenced in at least one approved generic drug submission. Section 744B(b)(2)(D) of the FD&C Act specifies the API facility fee will make up 6 percent of $582,500,000 in fee revenue, which is $34,950,000.

To calculate the API facility fee, data from FDA's IS were utilized as the primary source of facility information for determining the denominator. As stated above, IS is the master data steward for all facility information provided in generic drug submissions received by FDA. A facility's reference status in an approved generic drug submission is extracted directly from submission data rather than relying on data from self-identification. This information provided the number of facilities referenced as API manufacturers in at least one approved generic drug submission.

The total number of API facilities identified was 688; of that number, 80 were domestic and 608 were foreign facilities. The foreign facility differential is $15,000. To calculate the fee for domestic facilities, FDA must first subtract the fee revenue that will result from the foreign facility fee differential. FDA takes the foreign facility differential ($15,000) and multiplies it by the number of foreign facilities (608) to determine the total fee revenue that

will result from the foreign facility differential. As a result of this calculation, the foreign fee differential revenue will make up $9,120,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue ($9,120,000) from the total API facility target revenue ($34,950,000) results in a remaining balance of $25,830,000. To determine the domestic API facility fee, we divide the $25,830,000 by the total number of facilities (688), which gives us a domestic API facility fee of $37,544. The foreign API facility fee is $15,000 more than the domestic API facility fee, or $52,544.

F. Generic Drug Applicant Program Fee

Under GDUFA III, if a person and its affiliates own at least one but not more than five approved ANDAs on October 1, 2022, the person and its affiliates shall owe a small business GDUFA program fee. If a person and its affiliates own at least 6 but not more than 19 approved ANDAs, the person and its affiliates shall owe a medium size operation GDUFA program fee. If a person and its affiliates own at least 20 approved ANDAs, the person and its affiliates shall owe a large size operation GDUFA program fee. Section 744B(b)(2)(E) of the FD&C Act specifies the GDUFA program fee will make up 36 percent of $582,500,000 in fee revenue, which is $209,700,000.

To determine the appropriate number of parent companies for each tier, FDA asked companies to claim their ANDAs and affiliates in the Center for Drug Evaluation and Research (CDER) NextGen Portal. The companies were able to confirm relationships currently present in FDA's records, while also reporting newly approved ANDAs, newly acquired ANDAs, and new affiliations.

In determining the appropriate number of approved ANDAs, FDA has factored in a number of variables that could affect the collection of the target revenue: (1) inactive ANDAs: applicants who have not submitted an annual report for one or more of their approved applications within the past 2 years; (2) Program Fee Arrears List: parent companies that are on the arrears list for any fiscal year; (3) Large Tier Adjustment: the frequency of large-tiered companies dropping to the medium tier and medium-tiered companies moving to the large tier after the completion of the program fee methodology and tier determination; (4) Center for Biologics Evaluation and Research (CBER) approved ANDAs: applicants and their affiliates with CBER-approved ANDAs in addition to CDER's approved ANDAs; and (5) withdrawals of approved ANDAs by April 1: applicants who have submitted a written request for withdrawal of approval by April 1 of the previous fiscal year.

The list of original approved ANDAs from the Generic Drug Review Platform as of April 30, 2022, shows 253 applicants in the small business tier, 75 applicants in the medium size tier, and 79 applicants in the large size tier. Factoring in all the variables, we estimate there will be 220 applicants in the small business tier, 76 applicants in the medium size tier, and 77 applicants in the large size tier for FY 2023.

To calculate the GDUFA program fee, GDUFA III provides that large size operation generic drug applicants pay the full fee, medium size operation applicants pay two-fifths of the full fee, and small business applicants pay one-tenth of the full fee. To generate the target collection revenue amount from GDUFA program fees ($209,700,000), we must weigh medium and small tiered applicants as a subset of a large size operation generic drug applicant. FDA will set fees based on the weighted estimate of 22 applicants in the small business tier (220 multiplied by 10 percent), 30.4 applicants in the medium size tier (76 multiplied by 40 percent), and 77 applicants in the large size tier, arriving at 129.4 total weighted applicants for FY 2023.

To generate the large size operation GDUFA program fee, FDA divides the target revenue amount of $209,700,000 by 129.4, which equals $1,620,556. The medium size operation GDUFA program fee is 40 percent of the full fee ($648,222), and the small business operation GDUFA program fee is 10 percent of the full fee ($162,056).

IV. Fee Schedule For FY 2023

The fee rates for FY 2023 are set out in table 2.

TABLE 2—FEE SCHEDULE FOR FY 2023

Generic drug fee category	Fees rates for FY 2023
Applications:	
Abbreviated New Drug Application (ANDA)	$240,582
Drug Master File (DMF)	78,293
Facilities:	
Active Pharmaceutical Ingredient (API)—Domestic	37,544
API—Foreign	52,544
Finished Dosage Form (FDF)—Domestic	213,134
FDF—Foreign	228,134
Contract Manufacturing Organization (CMO)—	51,152
Domestic:	
CMO—Foreign	66,152
GDUFA Program:	
Large size operation generic drug applicant	1,620,556
Medium size operation generic drug applicant	648,222
Small business operation generic drug applicant	162,056

V. Fee Payment Options and Procedures

The new fee rates are effective October 1, 2022, and will remain in effect through September 30, 2023. Under sections 744B(a)(4) and (5) of the FD&C Act, respectively, facility and program fees are generally due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations act providing for the collection and obligation of GDUFA fees for the fiscal year. Here, that date is October 3, 2022. However, given the late date of the GDUFA reauthorization for FYs 2023 through 2027, facility and program fees for FY 2023 should be paid within 30 days from the issue date of this notice.

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