United States Food and Drug Administration

TOTAL PRODUCT LIFE CYCLE ADVISORY PROGRAM PILOT
OMB Control No. 0910-NEW

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, Agency, or we), Center for Devices and Radiological Health (CDRH or Center) collection under the Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot.

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[1] (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. 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.

A key goal of the TAP Pilot is to improve various aspects of medical device development and to increase the predictability and reduce the time from concept to commercialization, in part, by facilitating robust engagement early in the process with FDA, industry, and key stakeholders.

The MDUFA V commitment letter states the FDA will conduct an assessment of the overall outcomes of the TAP Pilot that will include a participant satisfaction survey and quantitative and qualitative success metrics that include, but are not limited to: (a) the extent to which FDA is successful at meeting the quantitative goals described in V.J.3.b[3] of the MDUFA V commitment letter; (b) participant satisfaction with 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.

We therefore request OMB approval of the information collections associated with the TAP Pilot, including the application to participate, participant satisfaction survey, participant pulse surveys, and interviews with participants, including passive observations of interactions as part of the TAP Pilot.

[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] 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.

2. Purpose and Use of the Information Collection

FDA's Center for Devices and Radiological Health (CDRH) launched the voluntary Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot in 2023. (87 FR 61605; October 12, 2022).

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 accelerated and widespread patient access to safe, effective, high-quality medical devices of public health importance.

TAP Pilot participants consist of both applicants (manufacturers) and external stakeholders, such as professional societies, payers, and patient advocacy groups. Data collected will inform the overall assessment of outcomes of the TAP Pilot. All information collection elements of the TAP Pilot will be conducted by FDA staff and/or contractors.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that 100% of the respondents will use electronic means to request approval to participate. FDA will utilize a technological solution for this collection in the form of an online, application portal. All surveys administered under this information collection will use automated information technology to collect and process information to reduce the burden on the public. FDA plans to collect the information using a web-based platform, such as SurveyMonkey. FDA plans to distribute pulse surveys electronically, primarily via email or through links posted in messages during teleconferences.

Any interview administered under this information collection will as appropriate, utilize automated information technology to collect and process information to reduce the burden on the public. FDA intends to conduct interviews virtually using Microsoft Teams or equivalent platform (e.g., Zoom.gov). Notes and transcripts will be captured via automated transcription applications available in Microsoft Teams and Microsoft Word where possible to reduce administrative burden.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

Based on the guidelines set by the Small Business Administration (SBA) on what constitutes a small business (for manufacturing, a small business cannot exceed 500 employees), we estimate that approximately 95% of U.S. medical device manufacturing establishments may be small businesses.

This is a voluntary program; therefore, manufacturers are not required to participate.

A key goal of the TAP Pilot is to improve various aspects of medical device development, including for participating small businesses, and to increase the predictability and reduce the time from concept to commercialization, in part, by facilitating robust engagement early in the process with FDA, industry and key stakeholders.

FDA aids small businesses in dealing with the regulations by providing guidance and information through CDRH's Division of International and Consumer Education (DICE). DICE provides

technical and non-financial assistance to firms through a comprehensive program including seminars, educational conferences, printed and electronic information materials, and via e-mail and a toll-free telephone number. Other CDRH staff members are also available to respond to questions. Alternatively, FDA may provide assistance through its Regional Small Business Representatives. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Respondents will submit information once when they initially apply to participate in the program, and they may apply to add additional devices on an occasional basis.

FDA will survey TAP Pilot participants twice annually after acceptance into the program. Collecting these data less frequently would increase the risk of bias or inaccuracy due to forgetting from respondents, as interactions occur throughout the year. Collecting data less frequently would also limit FDA's ability to demonstrate any trends over time or improvement in outcomes as a result of participating in the program, limiting the effectiveness and information to be included in the MDUFA V-required report.

FDA will provide opportunities to participate in interviews twice annually, after voluntarily taking the TAP Pilot Participant satisfaction survey and opting in for an interview. The purpose of the interviews is to clarify any feedback or response information provided in the survey, better understand the TAP Pilot participants experience in the program and identify areas of improvement and potential solutions. Collecting information less frequently would increase the risk of misinterpreting survey data or responses, as an aim of the interviews is to probe further into respondents' survey answers. It would also limit FDA's ability to show trends over time and decrease the accuracy of the information collected.

Observations of TAP Pilot participant interactions will be collected during interactions. All data collected from these observations will be analyzed and synthesized with other data to inform the assessment of the TAP Pilot. Data collected via observation allows for greater veracity of findings. Collecting this data less frequently may skew or otherwise bias data captured during observations.

FDA intends to also survey TAP participants closely following program interactions including teleconferences or requests for written feedback from FDA. The data from these "pulse surveys" is intended to show trends over time and measure satisfaction from different participants (e.g., applicants who entered the program at different points during the fiscal year). Multiple surveys are required to ensure data related to the interaction is captured immediately after the interaction occurs. Capturing feedback closer in time post-interaction will help gather more accurate satisfaction data and show trends over time, while administering a survey after each interaction will ensure there is data reflective of different interaction types and different participants. Therefore, administering the survey less frequently would provide FDA with less frequent and less differentiated data, posing a risk to the validity and completeness of the final assessment provided.

For all data collection methods mentioned above, the consequences if the collection is not conducted or conducted less frequency are that it would negatively impact the ability for FDA to comply with their commitments made as part of MDUFA V, namely, to conduct an assessment of the overall outcomes of TAP Pilot and publish a report of findings no later than January 30, 2026.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

FDA published a 60-day notice for public comment in the *Federal Register* of 03/21/2024 (89 FR 20209). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via the TAP Application Portal (webform) is participant name, email address, and business telephone number. Individuals completing the TAP Application will complete it via the webpage where a notice is displayed. TAP Pilot Customer Satisfaction Survey respondents who opt to provide PII will submit name, email address, business address, and business telephone number. Individuals completing the Observational Meeting Form will provide sponsor and attendee names. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.—Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
TAP Pilot Manufacturers requesting to participate	225	1	225	.25	56
Satisfaction Survey Participants	200	2	400	.33 (20 minutes)	132
TAP Pilot Participant Interviews	60	1	60	1	60
Passive Observations	100	1	100	0	0
Pulse Survey Participants	105	1	105	.03 (2 minutes)	3
Total[2]					251

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] Totals may not sum due to rounding.

FDA estimates that approximately 225 manufacturers will submit a request to participate in the TAP Pilot. Any sponsors who participate in the TAP Pilot will be invited to take the survey. As such, there is no sampling plan; the whole population of TAP Pilot participants will be invited to participate. TAP Pilot participants consist of both applicants and external stakeholders, such as professional societies, payers, and patient advocacy groups.

We estimate that approximately 200 manufacturers will qualify and therefore will be surveyed 2 times per year. In addition, around 60 manufacturers will be interviewed after completing an application to participate. Manufacturers will also be surveyed 1 additional time per year just to gage satisfaction over time with their experience interacting with FDA. This equates to 251 burden hours per year (rounded).

Application to Participate in TAP Pilot Program

The FDA is developing a software portal mechanism through which sponsors interested in device enrollment into the TAP Pilot program can submit an application to join.

TAP Pilot Participant Satisfaction Survey

This assessment includes a participant survey utilizing quantitative and qualitative success metrics. Data collected under this survey will help FDA evaluate the TAP Pilot. Specifically, FDA seeks to evaluate:

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

Any sponsors who participate in the TAP Pilot will be invited to take the survey.

TAP Pilot Participant Interviews

In support of qualitative success metrics and sentiments around the operation of the TAP Pilot, the FDA seeks to conduct interviews with TAP Pilot participants, including applicants and external stakeholders, such as professional societies, payers, and patient advocacy groups. The purpose of these interviews is to better understand individual participants' experiences in the TAP Pilot. Data collected in these interviews will help FDA understand the impact of the TAP Pilot and potential opportunities for improvement in TAP processes and operations. All TAP Pilot participants will make up the potential group of respondents for the interviews, however FDA intends to only interview a stratified sample of all potential participants.

TAP Pilot Passive Observations

FDA would like to obtain interaction-related data by passively observing meetings between FDA staff, applicants, and external stakeholders. Passive observations impose no burden on respondents, as they are solely conducted by FDA staff without requiring any input or action from the respondents. We plan to use a structured observational meeting form or checklist to standardize data collection. The purpose of these observations is to evaluate meeting attendance, level of collaboration and the degree to which key processes and activities are being adhered. Data collected may also support identification of improvement opportunities to the TAP Pilot. We do not intend to actively collect information from meeting participants directly (e.g., by asking questions or collecting documents).

TAP Pilot Participant Pulse Surveys

The FDA seeks to obtain quantitative satisfaction ratings and free-response data from TAP Pilot participants using a 2-question survey deployed closely following TAP Pilot interactions (e.g., teleconferences, written feedback). The same pulse survey will be administered after each interaction. The purpose of these surveys is to measure level of satisfaction with the interaction and allow for an opportunity for participants to provide feedback regarding the interaction.

12b. Annualized Cost Burden Estimate

The estimated annual reporting cost to respondents is $50,038. The information collection will be completed by Executives and by Regulatory Affairs Professionals. For Executives, we use the hourly wage rate of $237.[4] For Regulatory Affairs Professionals, we use the hourly wage rate of ($157).[5] We assume approximately 50 percent of respondents in each wage category.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Executives	125.5	$237	$29,743.50
Regulatory Affairs Professionals	125.5	$157	$19,703.50
Total			$49,447

[4] The estimated wage rate for Executives is based on the Bureau of Labor Statistics (BLS) mean hourly wage rate of $118.48 for Chief Executives (occupation code 11-1011) from the May 2022 National Occupational Employment and Wage Estimates data (https://www.bls.gov/oes/current/oes_nat.htm), then doubled to reflect the full cost of labor, including benefits and overhead, and rounded to the nearest dollar.

[5] The estimated wage rate for a Regulatory Affairs Professional is based on The Bureau of Labor Statistics (BLS) mean hourly wage rate of $78.74 for Lawyers (occupation code 23-1011) from the May 2022 National Occupational Employment and Wage Estimates data (https://www.bls.gov/oes/current/oes_nat.htm), then doubled to reflect the full cost of labor, including benefits and overhead, and rounded to the nearest dollar.

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital costs or operating and maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

FDA has partnered with an external third-party contractor to conduct the above-mentioned surveys, interviews, observations, and overall assessment. Annualized cost, as based on the price of the firm fixed-price contract, is $583,300.00.

We also assume associated FDA staff costs as follows:

- 5 minutes to administer the participant satisfaction survey twice annually to 200 participants, totaling to 33.33 hours per fiscal year. The average hourly cost is $143.06, totaling to $4,768.19 annualized FTE cost.
- 5 minutes to administer the pulse survey 105 times to individual participants, totaling to 8.75 hours per fiscal year. The average hourly FTE cost is $143.06, totaling to $1,251.78 annualized FTE cost.
- The time for managing the contract, including meetings, reviewing data/analyses, and editing and publishing the final report is estimated to be 5 hours weekly, totaling to 260 hours annually. The average hourly FTE cost is 143.06, totaling to $34,856 annualized FTE cost.

FDA costs are based on an internal cost model that assumes a fully-loaded, annual cost of $297,561 per position. The hourly cost is based on 2,080 hours per year.

We estimate the total annual Federal costs for the contract and FDA staff to be $624,175.97.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Per MDUFA V commitments, the information obtained from these data collection methods will be aggregated, synthesized, documented and publicly published on FDA website no later than January 30, 2026. To abide by this timeline, we plan to include data captured starting in FY2024 through Q4 of FY2025 to prepare the report in Q1 of FY2026 for ultimate publication on FDA website by January 30, 2026. We may continue data collection after publication of the report, through FY27, as needed, to support additional program improvement. However, FDA does not plan to publish any information formally, beyond the report required by MDUFA V described above, at this time.

Summary information related to measures of satisfaction, trends over time, and other aggregated survey responses may be shared periodically or ad hoc via meetings or written communications with industry stakeholders. No identifiable information about companies, organizations, or individuals will be shared publicly in any format. Information from the survey will inform improvement opportunities and process/program changes regarding TAP.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB control number and expiration date on the collection instruments, as required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.