4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-1201]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Total Product Life Cycle Advisory Program Pilot

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The title of this information collection is Voluntary Total Product Life Cycle Advisory Program Pilot. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Voluntary Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot

OMB Control Number 0910-NEW

This information collection supports the TPLC TAP. FDA's Center for Devices and Radiological Health launched the voluntary 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 fiscal year (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 that 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: (1) 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; (2) participant satisfaction with the timeliness, frequency, quality, and

---

[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 V.J.3.b 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.

efficiency of interactions with and written feedback from FDA; (3) participant satisfaction with the timeliness, frequency, quality, and efficiency of voluntary interactions with non-FDA stakeholders facilitated by FDA (if utilized); and (4) an overall assessment of the outcomes of the TAP Pilot and opportunities for improvement.

In the *Federal Register* of March 21, 2024 (89 FR 20209), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

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	0.25 (15 minutes)	56
Satisfaction Survey Participants	200	2	400	0.33 (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	0.03 (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.

Upon further review of the proposed information collection, we updated the burden table to include a distinct line item for Passive Observations for the TAP Pilot and to adjust the estimated number of respondents expected for the Pulse Survey.

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

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 FDA;
- participant satisfaction with the timeliness, frequency, quality, and efficiency of voluntary interactions with non-FDA stakeholders facilitated by FDA (if utilized); and
- other outcomes of the TAP 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, 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 interview only 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

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.

Dated: June 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-13961 Filed: 6/25/2024 8:45 am; Publication Date: 6/26/2024]