Research's Approved Cellular and Gene Therapy Products website at *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–03211 Filed 2–17–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1812]

Agency Information Collection Activities; Proposed Collection; Comment Request; Q-Submission and Early Payor Feedback Request Programs and Medical Device Development Tools

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 March 20, 2026.

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 OMB control number for this information collection is 0910–0756. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Q-Submission and Early Payor Feedback Request Programs and Medical Device Development Tools

OMB Control Number 0910–0756—Revision

The guidance entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' (May 2025) (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program*) provides an overview of the mechanisms available to submitters through which they can request feedback from or a meeting with FDA regarding certain potential or planned medical device submissions reviewed by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The guidance provides recommendations regarding certain types of Q-Submissions, such as Pre-Submissions, Submission Issue Requests, Study Risk Determinations, Informational Meetings, and other Q-Submission Types and other uses of the Q-Submission Program.

Recent updates in May 2025 to the Q-Submission guidance moved the instructions for information collection related to requests for feedback regarding development of a Medical Device Development Tool (MDDT), which were previously tracked as Informational Meeting Q-Submissions. We are revising this information collection to add the FDA guidance entitled ''Qualification of Medical Device Development Tools: Guidance for Industry, Tool Developers, and Food and Drug Administration Staff'' (July 2023) (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/qualification-medical-device-development-tools*), which includes instructions for submitting requests for feedback regarding MDDTs. The submission instructions are otherwise unchanged, but the MDDT guidance is now the collection instrument associated with the existing MDDT burden.

Early Payor Feedback Program

Prior to submitting a Pre-Submission, medical device sponsors may request that one or more payor organizations join a Pre-Submission meeting. Payors include public payors such as Centers for Medicare & Medicaid Services, private health plans, health technology assessment groups, and others who provide input into coverage, procurement, and reimbursement decisions. To facilitate such opportunities to obtain payor input, FDA provides information about our Early Payor Feedback Program (EPFP) and a list of current payor participants on our website (available at *https://www.fda.gov/about-fda/cdrh-innovation/payor-communication-task-force#2*). For payors to decide which devices to provide feedback on, we have developed a voluntary form for manufacturers to provide basic information regarding their device. This form is shared with the payors from whom the manufacturer is requesting feedback.

eSTAR for Q-Submissions

Under section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k–1(b)), amended by section 207 of the FDA Reauthorization Act of 2017 (Pub. L. 115–52), and consistent with the Medical Device User Fee Amendments 2017 (MDUFA IV) Commitment Letter and the FDA guidance document entitled ''Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act'' (July 2020) (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab*), FDA has developed an ''electronic Submission Template and Resource'' (eSTAR) for Q-submissions to facilitate the preparation of submissions in electronic format (available at *https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program*). The use of eSTAR for Q-Submissions is currently voluntary.

In the **Federal Register** of July 14, 2025 (90 FR 31225), 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] [2]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"					
Q-Submissions:					
CDRH	5,750	1	5,750	137	787,750
CBER	60	1	60	137	8,220
Q-Submissions using eSTAR:					
CDRH	850	1	850	69	58,650
CBER	40	1	40	69	2,760
eSTAR setup	1,480	1	1,480	0.08 (5 minutes)	118
Early Payor Feedback Program (EPFP)					
Manufacturer request to participate in EPFP	35	1	35	2	70
Medical Device Development Tools (MDDT)					
MDDT Submissions	50	1	50	137	6,850
Total					864,418

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

Based on our experience with the Q-Submission and Early Payor Feedback Request Programs and Medical Device Development Tools, our estimated burden for the information collection reflects an overall increase of 451,180 hours and 4,535 responses annually. We attribute this adjustment to an increase in the number of respondents according to FDA data. As discussed above, recent updates to the Q-Submission guidance moved the instructions for information collection related to requests for feedback regarding development of MDDTs to the MDDT guidance. MDDT proposal and qualification packages were previously tracked as Informational Meeting Q-Submissions. The MDDT submission instructions and previously approved burden estimate are otherwise unchanged, but the MDDT guidance is now the collection instrument associated with the existing MDDT burden. Accordingly, we have moved the burden for MDDT submissions to a distinct line item in the burden table to reflect the updated collection instrument. There is no new collection of information occurring in this revision. However, submissions related to MDDTs (Medical Device Development Tools), which were previously tracked as ''Informational Meetings'' Q-Submissions, are now tracked separately.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–03096 Filed 2–17–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1055]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, us, 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 March 20, 2026.

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 OMB control number for this information collection is 0910–0847. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–1244, *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.

Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

OMB Control Number 0910–0847—Extension

This information collection is intended to support FDA-conducted research. Understanding patients, consumers, and healthcare professionals' perceptions and behaviors plays an important role in improving FDA's regulatory decision-making processes and communications that affect various stakeholders. FDA uses the following methodology to achieve these goals: (1) creation and validation of survey instruments; (2) use of techniques to evaluate sampling and recruitment methods; (3) evaluation of the validity and reliability of survey instruments; (4) individual in-depth interviews; (5) general public focus group interviews; (6) intercept interviews; (7) self-administered surveys; (8) gatekeeper surveys; and (9)