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]

BILLING CODE 4164–01–P

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)

focus group interviews. These methods serve the narrowly defined need for direct and informal opinion on a specific topic and serve as a qualitative and quantitative research tool having two major purposes:

- Obtaining useful, valid, and reliable information for the development of variables and measures for formulating the basic objectives of social and behavioral research; and
- Successfully communicating and addressing behavioral changes with intended audiences to assess the potential effectiveness of FDA communications, behavioral interventions, and other materials.

While FDA will use these methods to test and refine its ideas and help develop communication and behavioral strategies research, the Agency will generally conduct further research before making important decisions (such as adopting new policies and allocating or redirecting significant resources to support these policies).

FDA's Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research, Office of the Commissioner, and any other Centers will use this mechanism to test communications and social and behavioral methods about regulated drug products on a variety of subjects related to consumer, patient, or healthcare professional perceptions, beliefs, attitudes, behaviors, and use of drug and biological products and related materials. These subjects include social and behavioral research, decision-making processes, and communication and behavioral change strategies.

Further, in addition to overseeing the safety of drug products when used according to approved drug labeling or as directed by a healthcare provider, CDER conducts studies on topics related to the safe and effective use of drug products, and emerging safety issues in areas such as: (1) nonmedical use of approved drug products; (2) use of unapproved and falsified (*i.e.,* counterfeit, fake) drug products; (3) use of botanical substances (*e.g.,* cannabis derived products); (4) controlled substance prescribing decisions; (5) bystander response to drug overdoses; and (6) potentially false or misleading information about drug products. Reliable data on these and related topics are a critical first step to understanding whether further studies or action is needed to protect public health.

Because often data on these topics are not collected as part of routine healthcare delivery or via established Federal surveys, FDA requires the development and validation of novel instruments (*i.e.,* interview and focus group guides, questionnaires) and approaches to gathering data on emerging safety issues the methods used to create and validate these instruments may include interviews, focus groups, small group discussions, pilot and test/re-test survey launches, and external validation against benchmark surveys. In conducting research in these areas, FDA will need to employ the following validation methodology: (1) research to assess knowledge, perceptions, and experiences related to topics in the above-mentioned areas with specific target populations; (2) techniques to evaluate sampling and recruitment methods; and (3) evaluations of the validity and reliability of survey questionnaires in target populations.

Annually, FDA projects about 25 social and behavioral studies using the variety of test methods listed in this document. FDA is revising this burden to account for the number of studies we have received in the last 3 years and to better reflect the scope of the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews and Surveys	126,770	1	126,770	0.25 (15 minutes)	31,693

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

Based on a review of the information collection since our last request for OMB approval, our burden estimate for this information collection reflects an overall increase of 17,300 responses with a corresponding increase of 4,325 hours. We attribute this adjustment to the need to validate information in specific areas.

In accordance with 5 CFR 1320.8(d), FDA published a 30-day notice for public comment on the proposed collection of information in the **Federal Register** on December 19, 2024 (89 FR 103841). FDA is reopening the 30-day comment period in order to satisfy PRA requirements. No changes have been made to the information collection.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–03099 Filed 2–17–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0497]

Agency Information Collection Activities; Proposed Collection; Comment Request; Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection relating to our Patent Term Restoration regulations.

DATES: Either electronic or written comments on the collection of information must be submitted by April 20, 2026.

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 April 20, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.