

submitted controlled correspondence. As described in the GDUFA III commitment letter, FDA has also agreed to review and respond to requests to clarify ambiguities in the controlled correspondence response, and the guidance provides information on how requestors can submit these requests and the Agency's process for responding to them.

This draft guidance revises the guidance for industry entitled "Controlled Correspondence Related to Generic Drug Development" issued in December 2020. When finalized, this updated guidance will replace the December 2020 guidance. Changes from the 2020 version include updating the guidance to reflect enhancements in the GDUFA III commitment letter (*e.g.*, including information on controlled correspondence that can be submitted during abbreviated new drug application assessment and after issuance of a complete response letter or a tentative approval or approval); providing additional recommendations on requests for information related to inactive ingredients; and other updates that are intended to clarify FDA's recommendations to industry.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Controlled Correspondence Related to Generic Drug Development." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0797, respectively.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda->

[guidance-documents](https://www.fda.gov/guidance-documents), or <https://www.regulations.gov>.

Dated: December 16, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2012–D–0530]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Q-Submission Program for Medical Devices

**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 January 23, 2023.

**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 Sanford, 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](mailto: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-Submissions Program for Medical Devices

OMB Control Number 0910–0756—Revision

The guidance entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" (<https://www.fda.gov/media/114034/download>) 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.

Respondents are medical device manufacturers subject to FDA's laws and regulations. FDA's annual estimate of 3,700 submissions is based on recent trends. FDA's administrative and technical staffs, who are familiar with Q-Submissions, estimate that an average of 137 hours is needed to prepare a Q-Submission.

#### 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 (<https://www.fda.gov/about-fda/cdrh-innovation/payor-communication-task-force>). 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. We expect preparation and submission of the form to take no more than 2 hours.

#### 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” (<https://www.fda.gov/media/131064/download>), FDA has developed an “electronic Submission Template and Resource” (eSTAR) for Q-submissions to facilitate the preparation

of submissions in electronic format (<https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program>). The use of eSTAR for Q-Submissions is currently voluntary. We assume approximately 40 percent of Q-Submissions will use eSTAR and that preparation using eSTAR will take approximately half the time of preparing a submission without using eSTAR.

We estimate a setup burden of 5 minutes for new eSTAR users. Respondents will only need to set up eSTAR the first time they use it. We

note that because some respondents may have already undergone eSTAR set up for other types of submission, e.g., premarket notification, fewer respondents may need to undergo eSTAR setup than estimated.

In the **Federal Register** of August 9, 2022 (87 FR 48488), 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 <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
<b>“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”</b>					
Q-Submissions:					
CDRH .....	2,160	1	2,160	137 .....	295,920
CBER .....	60	1	60	137 .....	8,220
<b>Q-Submissions using eSTAR (21 CFR part 814, subparts A through E; section 745A(b) of the FD&amp;C Act)</b>					
CDRH .....	1,440	1	1,440	69 .....	99,360
CBER .....	40	1	40	69 .....	2,760
eSTAR setup .....	1,480	1	1,480	0.08 (5 minutes)	118
Manufacturer request to participate in EPFP .....	30	1	30	2 .....	60
Total .....					406,438

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Including the EPFP form represents a revision to this information collection request. Our estimated burden for the information collection reflects the availability of eSTAR to assist electronic preparation of Q-submissions and addition of the EPFP form, resulting in an overall decrease of 85,803 hours.

Dated: December 16, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2022–N–3208]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Records and Reports Concerning Experiences With Approved New Animal Drugs: Adverse Event Reports**

**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 adverse event reporting by FDA on new animal drugs and product manufacturing defects.

**DATES:** Either electronic or written comments on the collection of information must be submitted by February 21, 2023.

**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 February 21, 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