4164-01-P

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 [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 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.

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

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[1]

Activity	No. of Respondents	No. 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	2,160	1	2,160	137	295,920
CBER	60	1	60	137	8,220
Q-Submissions using eSTAR (21 CFR part 814, subparts A through E; section 745A(b) of the FD&C Act):					

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
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"					
Q-Submissions:					
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

[1] 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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