



BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-6876]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Improvement Program

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 0910-0922. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kelly Covington, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-402-5661, PRASStaff@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.

Medical Devices; Voluntary Improvement Program

OMB Control Number 0910-0922--Extension

This information collection supports Food and Drug Administration (FDA, us or we) implementation of its Voluntary Improvement Program (VIP). Included among the strategic priorities of our Center for Devices and Radiological Health (CDRH) is promoting a culture of quality and organizational excellence. As communicated on our website at <https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/voluntary-medical-device-manufacturing-and-product-quality-pilot-program>, we conducted a pilot project pertaining to voluntary medical device manufacturing and product quality and have incorporated some of the successes and learnings into the VIP. The VIP oversees third-party appraisers who evaluate industry participants. The VIP is facilitated by the Medical Device Innovation Consortium (MDIC), a public-private partnership that evaluates the capability and performance of a medical device manufacturer's practices using third-party appraisals and is intended to guide improvement to enhance the quality of devices. As part of the VIP process, FDA receives information about participating device manufacturers' capability and performance for activities covered in third-party appraisals.

The guidance document entitled, “*Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program*,” communicates our policy regarding participation in the VIP. Only eligible manufacturers of medical devices regulated by CDRH whose marketing applications are reviewed under the applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (including sections 510(k), 513, 515, and 520) may participate in the VIP. The guidance document was developed and issued consistent with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. The guidance document includes instruction to respondents regarding eligibility, FDA engagement with participants, submission criteria, and withdrawal or removal from the program.

In the *Federal Register* of July 17, 2026 (91FR 44852), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received.

FDA received one comment from an individual. The commenter supported extending the VIP information collection and organized his remarks around the four questions in the 60-day notice, as summarized here:

The commenter affirmed the value of VIP appraisal data as a proactive quality signal and suggested FDA publish de-identified, aggregated benchmark data from appraisal results, particularly to assist smaller manufacturers of high-risk devices during the QMSR transition.

The commenter asserted that the 20-hour estimate for the summary of site appraisal is significantly low for first-time participants and recommended either splitting

the estimate into initial and repeat appraisal figures or surveying current VIP participants to validate it. The commenter also noted that if the estimate covers only the incremental reporting burden, the supporting statement should make that scoping assumption explicit. The commenter recommended (1) capturing repeat-nonconformance rates for issues previously closed through CAPA as a complement to maturity scores, and (2) adopting a standardized summary template to improve comparability across sites and appraisal cycles. The commenter suggested (1) offering a structured electronic submission form, (2) pre-populating identifying fields from existing establishment registration and device listing data, and (3) allowing repeat participants to submit delta reports covering only changes since the last appraisal.

FDA has taken note of the commenter's suggestion to publish de-identified, aggregated benchmark data derived from appraisal results. This information is currently available to VIP participants. As VIP is a voluntary improvement program, not a compliance program, participation data is submitted to FDA by the third-party appraiser with no commitment that it will be shared publicly. Accordingly, FDA does not plan to make this information available to the public at this time.

FDA acknowledges the commenter's concern regarding the accuracy of the 20-hour burden estimate for the summary of site appraisal, particularly as it applies to first-time participants. However, the 20-hour estimate refers to the time spent by the third-party appraiser, not the device manufacturer, to prepare and submit a summary of the site appraisal to FDA. Because this information collection captures the burden imposed on the third-party appraiser, the commenter's experience preparing manufacturing sites for appraisal does not directly relate to this estimate. FDA has not received any information

or feedback regarding the accuracy of this estimate of the burden on the third-party appraiser and no changes to this burden estimate are appropriate, based on the comment.

FDA also acknowledges the commenter's suggestion to provide estimates to separate initial vs. subsequent appraisals but has not received any information or feedback relating to accuracy of the 20-hour estimate for the third-party appraiser. (1) FDA has considered the commenter's recommendation to capture nonconformance rates for issues previously closed through CAPA. FDA acknowledges the comment that recurrence data may provide value not found in maturity scores alone. However, as VIP is a voluntary improvement program and not a compliance program, capturing either recurrence data or reasons for CAPA failure is outside the current scope of the information the program is designed to collect. (2) FDA agrees that comparability across sites and appraisal cycles can be useful under the proper circumstances. However, the VIP is structured so that participants work with the appraisers to create an individualized, mutually-agreed upon appraisal process. As such, each VIP participant firm may focus on a different set of quality measures as part of its appraisal process. As a result of these differences, there would be limited value in comparability across participants and FDA does not plan to make changes to the program to increase comparability.

FDA appreciates the commenter's suggestions for reducing respondent burden. As this is a third-party appraisal program, FDA relies on the third-party-appraiser's expertise in implementing a successful appraisal program including determining the method of collecting data and choosing the format of submissions. With respect to pre-populating fields from establishment registration and device listing data, FDA notes that, because these are independent third-party programs, appraisers do not necessarily have

direct access to FDA databases and submissions. Furthermore, VIP is not limited to one third party appraiser and may employ different appraisers using different methods.

Accordingly, FDA does not believe a common application form or a standardized delta-reporting format based on prior submissions would be appropriate.

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

Table 1.--Estimated Annual Reporting Burden

Recommended Information Collection Activity: <i>Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program</i>	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Site manufacturer application	1	300	300	0.08	24
Aggregate data reporting	1	4	4	8	32
Summary of site appraisal	1	300	300	20	6,000
Total					6,056

Our estimated burden for the information collection reflects an overall decrease of 2,009 hours and a corresponding decrease of 200 responses. We attribute this adjustment based on our device registration and listing data and informal feedback from stakeholders.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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