

United States Food and Drug Administration  
Medical Device User Fee Small Business Qualification and Certification  
OMB Control No. 0910-0508  
No Material or Non-Substantive Change to a Currently Approved Collection (83-C)

The Food and Drug Administration (FDA) is requesting non-substantive/non-material changes to OMB Control No. 0910-0508 to make available electronic submission of forms FDA 3602 and FDA 3602A. We believe this change request is consistent with OMB's guidance in its flexibility memorandum of July 22, 2016 (see p.5, *Example of Use of Non-Substantive Changes for Certain Web-based or Similar Applications*).

Currently, to apply for a Small Business Determination (SBD),<sup>1</sup> businesses must follow a paper-based application process and mail their certification requests, Forms [FDA 3602](#) (“MDUFA Small Business Certification Request for a Business Headquartered in the United States”) and [FDA 3602A](#) (“MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States”) to FDA. Forms FDA 3602 or 3602A are filled out in pdf format, then printed and submitted to FDA via physical mail.

We intend to change from paper to online submission of these forms using the Center for Devices and Radiological Health (CDRH) Customer Collaboration Portal (<https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal>). The move to online submission aims to streamline the SBD application process, eliminating physical mail and providing real-time review status. We have made no substantive changes to the forms' content or requested information; we have updated the instructions to reflect online submission. Also, in form FDA 3602A, we are removing duplicative and outdated PRA language at the end of the instructions (however, we are not making any changes to the correct PRA language that is already included on p.2). We are making no adjustment to our current burden estimates associated with the forms.

We plan to notify respondents and the public via email distribution and social media, and will update the information and instructions on FDA's website regarding reduced medical device user fees ([Reduced Medical Device User Fees: Small Business Determination \(SBD\) Program | FDA](#)) to reflect online submission of forms FDA 3602 and 3602A. FY 2025 requests may be submitted beginning August 1, 2024. We intend to make online submission available for FY 2025 SBD requests immediately upon OMB approval.

**Attachments:**

- Form FDA 3602 pdf (click on comments in the document for an explanation of change(s))
- Form FDA 3602A pdf (click on comments in the document for an explanation of change(s))
- Customer Collaboration Portal screen captures (click on comments in the document for an explanation of change(s))
- Email & social media outreach
- Updated website instructions

---

<sup>1</sup> Criteria FDA uses to decide whether an entity qualifies as a MDUFA small business and is eligible for a reduction in user fees and instruction on submitting relevant information to FDA are provided in the guidance document, “Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments” (April 2018), available at <https://www.fda.gov/media/93354/download> (see OMB control number 0910-0508).