& Medicaid Services (CMS) will make available a more detailed agenda and meeting materials no later than 3 days before the meeting on the AAQPS Committee website at *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/advisory-committee-air-ambulance-quality-and-patient-safety.*

III. Public Participation

The meeting is open to the public for virtual attendance on a first-come, first-served basis, as there may be capacity or technical limitations. Please see the **ADDRESSES** section to view the meeting link.

We are committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as a sign language interpreter, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section no later than 2 weeks before the meeting.

Presenting Oral Comments

CMS will accept oral comments, which must be limited to the objectives of the Committee and limited to 3 minutes per person. Individual members of the public who wish to present oral comments must register and provide a written copy of prepared remarks for inclusion in the meeting records and for circulation to AAQPS Advisory Committee members. All prepared remarks submitted on time will be considered as part of the meeting's record.

IV. Submitting Written Comments

Members of the public may submit written comments for consideration by the Committee at any time via email to *AAQPS@cms.hhs.gov.* Additionally, members of the public will have the opportunity to submit comments during the July 10, 2025, virtual meeting through the chat feature of the Zoom webinar platform. Members of the public are encouraged to email lengthy written comments to *AAQPS@cms.hhs.gov.* Advance submissions that are within the scope of the Advisory Committee will become part of the official record of the meeting.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Mehmet Oz, having reviewed and approved this document, authorizes Vanessa Garcia, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2025–10401 Filed 6–6–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1873]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Small Business Qualification and Certification

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 July 9, 2025.

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 0910–0508. 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.

Medical Device User Fee Small Business Qualification and Certification

OMB Control Number 0910–0508—Revision

This information collection helps support implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), most recently reauthorized in 2022 from October 1, 2022, until September 30, 2027. To qualify as a ''small business,'' and therefore be eligible for reduced or waived fees, respondents submit information to FDA so we can determine whether the applicant is a small business. Sections 738(d)(2)(A) and (e)(2)(A) of the FD&C Act (21 U.S.C. 379j(d)(2)(A) and (e)(2)(A)) define a ''small business'' as an entity that reported $100 million or less of gross receipts or sales in its most recent Federal income tax return, including such returns of its affiliates, partners, and parent firms. If a firm's gross receipts or sales are no more than $30 million (including all affiliates, partners, and parent firms), they will also qualify for a waiver of the fee for their first (ever) premarket application (PMA), product development protocol (PDP), biological licensing application (BLA), or premarket report.

In the **Federal Register** of February 22, 2024 (89 FR 13349), FDA announced the availability of the draft guidance for industry entitled ''Select Updates for the Medical Device User Fee Small Business Qualification and Certification Guidance'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-medical-device-user-fee-small-business-qualification-and-certification-guidance*). The guidance includes select updates to the guidance ''Medical Device User Fee Small Business Qualification and Certification'' (August 2018), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-certification*) which describe how FDA plans to determine if a small business is experiencing ''financial hardship'' that makes them eligible for a waiver of their registration fee. A manufacturer seeking the small business fee waiver may provide evidence of a reported $1 million or less of gross receipts or sales in its most recent Federal income tax return, as well as evidence that they have filed a petition for bankruptcy and that the bankruptcy is currently active. The proposed updates also reflect that firms based in jurisdictions without a National Taxing Authority (NTA) need not submit a

certification from their NTA to be eligible for fee waivers or reductions.

Additionally, FDA intends to consolidate the forms previously known as FDA 3602 and FDA 3602A into a single webform, the ''MDUFA Small Business Request'' (MDUFA SBR, FDA 3602N) to be completed by foreign as well as U.S. businesses/applicants via FDA's Center for Devices and Radiological Health Customer Collaboration Portal (CDRH Portal). We have also added to the MDUFA SBR a ''Registration & Listing Waiver'' section which asks if the business/applicant will apply for a registration and listing fee waiver and whether they have applied in the past. Applicants seeking this waiver will be asked to include proof of bankruptcy documentation in the supporting documentation section.

In the **Federal Register** of February 22, 2024 (89 FR 13349), FDA published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received, but they were not related to the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
MDUFA Small Business Request webform—FDA 3602N ..	4,500	1	4,500	1	4,500

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

As discussed previously in this document, we have proposed updates to the guidance document, ''Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments,'' (August 2018) consistent with amendments to section 738(a)(3)(B) of the FD&C Act. Because we assume that current bankruptcy documentation is readily available to applicants, we assume no change to the Average Burden per Response for this information collection.

Aside from the changes already discussed, the total burden estimate remains unchanged from the last OMB approval.

Dated: June 3, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–10387 Filed 6–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0937–0166]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 9, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Michelle Jasczynski, *Michelle.Jasczynski@hhs.gov,* (301) 284–6813. When submitting comments or requesting information, please include the document identifier 0937–0166–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: HHS 42 CFR subpart B; Sterilization of Persons in Federally Assisted Family Planning Projects.

Type of Collection: Renewal.

OMB No. 0937–0166.

Abstract: The Department of Health and Human Service, Office of Population Affairs is requesting an extension of a currently approved collection for the disclosure and recordkeeping requirements codified at 42 CFR part 50, subpart B (''Sterilization of Persons in Federally Assisted Family Planning Projects''). The consent form solicits information to assure voluntary and informed consent to persons undergoing sterilization in programs of health services which are supported by federal financial assistance administered by the United States Public Health Service (PHS). It provides additional procedural protection to the individual and the regulation requires that the consent form be a copy of the form that is appended to the PHS regulation. In 2003, the PHS sterilization consent form was revised to conform to OMB government-wide standards for the collection of race/ethnicity data and to incorporate the PRA burden statement as part of the consent form. We are requesting a three-year extension.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Information Disclosure for *Sterilization Consent Form.*	Citizens Seeking Sterilization	100,000	1	1	100,000