

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 BURDEN¹

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

ANNUALIZED BURDEN HOUR TABLE—Continued

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Record-keeping for <i>Sterilization Consent Form</i> .	Citizens Seeking Sterilization	100,000	1	15/60	25,000
Total	125,000

Catherine Howard,*Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.*

[FR Doc. 2025-10404 Filed 6-6-25; 8:45 am]

BILLING CODE 4150-34-P**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings.

Date: July 8–9, 2025.

Time: 10:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Heidi B. Friedman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 907-H, Bethesda, MD 20892, (301) 379-5632, hfriedman@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business—Anti-Infective Therapeutics.

Date: July 9–10, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institute of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Marcus Ferrone, PHARMD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402-2371, marcus.ferrone@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Assay Development, Drug Discovery Tools, and Imaging.

Date: July 9–10, 2025.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Angela Monique Boute, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 594-0063, boutteam@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Clinical Care and Health Interventions.

Date: July 10–11, 2025.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Trina Colleen Salm Ward, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-5254, salmwardtc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Genes, Genomes and Genetics.

Date: July 10–11, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Linda Wagner Jurata, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-8032, linda.jurata@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Applied Immunology and Vaccine Development.

Date: July 10–11, 2025.

Time: 10:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Dayadevi Jirage, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4422, Bethesda, MD 20892, (301) 867-5309, jiragedb@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 4, 2025.

Bruce A. George,*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2025-10426 Filed 6-6-25; 8:45 am]

BILLING CODE 4140-01-P**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Maximizing Investigators' Research Award.

Date: July 9–10, 2025.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.