



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-2549]

Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational Device Exemptions Reports and Records

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 0910-0078.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, 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.

Investigational Device Exemptions Reports and Records --21 CFR Part 812

OMB Control Number 0910-0078--Extension

This information collection supports implementation of section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), which governs exemption for devices for investigational use. An investigational device exemption (IDE) allows a device to be used in investigations involving human subjects in which the safety and effectiveness of the device is being studied. For more information regarding IDE, please visit our website at <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide>.

FDA has promulgated regulations in part 812 (21 CFR part 812) intended to encourage the discovery and development of useful devices intended for human use. The regulations set forth the scope and applicability of exemption requirements for devices for investigational use, as well as establish application procedures, corresponding instruction, and provisions for emergency research. The regulations also provide for requesting waivers from the requirements; and explain sponsor responsibilities, including requirements for institutional review board (IRB) review and approval. Finally, the regulations in part 812, subpart G (21 CFR 812.140, 812.145, and 812.150) provide for required recordkeeping, the inspection of records, and the preparation and submission of reports to FDA and/or IRBs that oversee medical device investigations. The information collection also includes recommended recordkeeping discussed in the document, “Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable” (April 2006), available for download at GFI IVD Leftover Specimens April 2006, and previously approved under OMB control no. 0910-0582. The guidance document explains that FDA does not intend to object to the use, without informed consent, of leftover human specimens -- remnants of specimens collected for routine clinical care or analysis that would otherwise have been discarded -- in investigations that meet the criteria for exemption in 21 CFR 812.2(c)(3), as long as subject privacy is protected by using only specimens that are not individually identifiable. The guidance document was developed and

Table 1.--Estimated Annual Reporting Burden^{1,2}

Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
812.10; waivers	1	1	1	1	1
812.20, 812.25, and 812.27; applications, investigational plans, and supplements	288	1	288	80	23,040
812.27(b)(4)(i); prior investigations within the United States	504	1	504	1	504
812.27(b)(4)(ii); prior investigations outside the United States	126	1	126	0.25 (15 minutes)	32
812.28; acceptance of data from clinical investigations conducted outside the United States, and supporting information	1,500	1	1,500	10.25	15,375
812.28(c);waivers	10	1	10	1	10
812.35 and 812.150; application supplements	824	5	4,120	6	24,720
812.36(c); treatment IDE applications	1	1	1	120	120
812.36(f); treatment IDE reports	1	1	1	20	20
812.150; non-significant risk study reports to third parties	1	1	1	6	6
Total			6,552		63,828

issued in accordance with our Good Guidance Practice regulations (21 CFR 10.115), which provide for public comment at any time.

In the *Federal Register* of August 22, 2025 (90 FR 41087) 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:

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

² Numbers have been rounded.

Table 2.--Estimated Annual Recordkeeping Burden^{1,2}

Activity/21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
812.2(c)(3); records regarding leftover specimens not individually identifiable used in certain studies	700	1	700	4	2,800
812.28(d); records for clinical investigations conducted outside United States	1,500	1	1,500	1	1,500
812.140; retention of records	1,249	3.09	3,859	1.9937	7,694
Total			6,059		11,994

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

² Numbers have been rounded.

Our estimated burden for the information collection reflects an overall increase of 9,919 hours and a corresponding increase of 1,033 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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