4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0576]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational Device Exemptions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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--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.

In the *Federal Register* of May 6, 2022 (87 FR 27168), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

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	229	1	229	80	18,320
812.27(b)(4)(i); prior investigations within the United States	400	1	400	1	400

Table 1.--Estimated Annual Reporting Burden[1]

Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
812.27(b)(4)(ii); prior investigations outside the United States	100	1	100	0.25 (15 minutes)	25
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	654	5	3,270	6	19,620
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	1	1	1	6	6
Total			5,513		53,897

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

Our estimate of the average reporting burden is based on our continued experience with the information collection. We have adjusted the currently approved burden to reflect an increase we attribute to Agency rulemaking that has become effective (OMB control number 0910-AG48) since our last evaluation. Regulations in part 812 were amended to provide for reporting associated with the acceptance of data from clinical investigations conducted outside the United States.

Table 2.--Estimated Annual Recordkeeping Burden[1]

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	3,865	1.9937	7,706
Total					12,006

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

In the guidance document "Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable" (April 2006), available for download at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-informed-consent-vitro-diagnostic-device-studies-using-leftover-human-specimens-are-not, FDA communicates its enforcement policy with regard to the informed

consent regulations (as required by section 520(g) of the FD&C Act and 21 CFR part 50) for in vitro diagnostic device studies that are conducted using leftover specimens and that meet the criteria for exemption from IDE regulation at 21 CFR 812.2(c)(3). We include burden that may be attributable to FDA recommendations that sponsors of studies document certain information, in table 2, row 1. We have otherwise adjusted our estimate upward of the average recordkeeping burden attributable to provisions in part 812 to reflect those requirements associated with clinical investigations conducted outside the United States, and in recognition of the required retention period for records.

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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