4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-1109]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization

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 0910-0607. Also include the FDA docket number found in brackets in the heading of this document.

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.

Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization

OMB Control Number 0910–0607--Extension

This information collection helps support implementation of statutory provisions applicable to laboratories that conduct testing on human specimens under CLIA. These requirements are codified in 42 U.S.C. 263a and implementing regulations are found in 42 CFR 493. Regulations in 42 CFR 493.17 set forth certain notice requirements and establish test categorization criteria for laboratory tests and are implemented by FDA's Center for Devices and Radiological Health. The guidance document entitled "Administrative Procedures for CLIA Categorization" (October 2017) (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/administrative-procedures-clia-categorization*) describes procedures FDA uses to assign the complexity category to a device. Typically, FDA assigns complexity categorizations to devices at the time of clearance or approval of the device. In some cases, however, a manufacturer may request CLIA categorization even if FDA is not simultaneously reviewing a 510(k) or premarket approval application. One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (e.g., name change, exempt from 510(k) review). The guidance recommends that in the correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available.

In addition, this information collection includes provisions associated with certificates of waiver. The guidance document entitled "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro

Diagnostic Devices—Guidance for Industry and FDA Staff" (February 2020) (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-clinical-laboratory-improvement-amendments-1988-clia-waiver-applications*) describes recommendations for device manufacturers submitting to FDA an application for determination that a cleared or approved device meets this CLIA standard (CLIA waiver application). The guidance recommends that CLIA waiver applications include a description of the features of the device that make it "simple"; a report describing a hazard analysis that identifies potential sources of error, including a summary of the design and results of flex studies and conclusions drawn from the flex studies; a description of fail-safe and failure alert mechanisms and a description of the studies validating these mechanisms; a description of clinical tests that demonstrate the accuracy of the test in the hands of intended operators; and statistical analyses of clinical study results.

In the *Federal Register* of July 3, 2025 (90 FR 29568), 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:

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

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Total Operating and Maintenance Costs
Request for CLIA Categorization	86	5	430	1	430	$2,150
CLIA Waiver Application Submissions	20	1	20	1,200	24,000	$540,000
Total					24,430	$542,150

[1] There are no capital costs associated with this collection of information.

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

Information Collection Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
CLIA Waiver Recordkeeping as discussed in FDA Guidance	20	1	20	2,800	56,000

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

FDA estimates an increase of 30 responses for requests for CLIA categorization and 7 responses for waiver application submission based on recent FDA receipt data to more accurately reflect recent receipts of requests for CLIA categorization and CLIA waiver application submissions. Our total burden for this collection will be 80,430 hours (24,430 reporting + 56,000 recordkeeping). Our estimated burden for the information collection reflects an overall increase of 28,030 hours and a corresponding increase of $190,150 total operating and maintenance costs.

Lowell M. Zeta,

Acting, Deputy Commissioner for Policy, Legislation, and International Affairs

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