Administrative Procedures for
Clinical Laboratory Improvement Amendments of 1988 (CLIA) Categorization

OMB Control No. 0910-0607 - Extension

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection helps support implementation of statutory provisions applicable to laboratories that conduct testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (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, previously approved under control no. 0910-0598. 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.

We therefore request extension of OMB approval of the information collections associated with administrative procedures for CLIA categorization codified in 42 U.S.C. 263a and 42 CFR 493.17 and explained in the guidance entitled "Administrative Procedures for CLIA Categorization" (October 2017), as well as for provisions associated with CLIA certificates of waiver as explained in the guidance "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), as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

FDA uses the information collected to determine device complexity, and to post in the FDA CLIA Database (available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm*) for use by the public, including laboratories, and regulatory agencies. We also use the information to determine whether a device is waived under CLIA. Respondents to the information collection are from the private sector (for-profit and not-for-profit businesses), specifically manufacturers of in vitro diagnostic devices applying for "CLIA waived" designation of a device.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that respondents will submit 50% of CLIA categorization requests and related information, and 100% of CLIA waiver submissions and related information through the e-Copy Program. The guidance "eCopy Program for Medical Device Submissions" (April 2020) (available at *https://www.fda.gov/media/83522/download*) describes the eCopy Program under section 745A(b) of the FD&C Act. The inclusion of an eCopy improves the efficiency of the review process by allowing for the immediate availability of an electronic version for review rather than relying solely on the paper version. eCopies can be on a single CD, DVD, or flash drive. The guidance instructs the applicant to submit it to FDA, CDRH Document Control Center.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection poses undue burden on small entities.

6. Consequences of Collecting the Information Less Frequently

The information collection is consistent with statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with the information collection.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the *Federal Register* of July 3, 2025 (90 FR 29568), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974 (5 U.S.C. 552a)

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted is the name, work email address, work telephone number, and work address of the appellant. Although this PII is collected, we have determined that this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected. Through appropriate design, FDA minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public (see 21 CFR 20), consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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
Request for CLIA Categorization	86	5	430	1	430
CLIA Waiver Application Submissions	20	1	20	1,200	24,000
Total					24,430

[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
Total					56,000

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

The regulations in 42 CFR 493.17 and the associated guidance documents describe specific content elements necessary for FDA action on request for CLIA categorization submissions. Based on recent trends, an estimated 86 requests for CLIA categorization are expected each year. Our administrative and technical staff, who are familiar with the requirements for submission of premarket notifications, estimate that it takes an average of 1 hour to prepare and submit a submission. Because the PRA defines a recordkeeping requirement to include reporting those records to the Federal government (5 CFR 1320.3(m)), we account for burden associated with preparing, transmitting, and responding to follow-up requests from FDA for supplemental information in our estimate.

The regulations in 42 CFR 493.15 and 493.17 and the associated guidance documents describe specific content elements recommended to be found in CLIA waiver submissions. Based on recent trends, an estimated 20 submissions are expected each year. Our administrative and technical staff, who are familiar with the requirements for submission of CLIA waiver submissions, estimate that it takes an average of 2800 hours to prepare and submit a submission. Because the PRA defines a recordkeeping requirement to include reporting those records to the Federal government (5 CFR 1320.3(m)), we account for burden associated with preparing, transmitting, and responding to follow-up requests from FDA for supplemental information in our estimate.

12b. Annualized Cost Burden Estimate

We assume the activities identified in 12a will be completed by Lawyers (occupation code 23-1011) (approximately 50% of tasks) and Paralegals (occupation code 23-2011) (approximately 50% of tasks). To estimate costs to respondents, we used mean wage rates from the U.S. Department of Labor's Bureau of Labor Statistics National Occupational Employment and Wage Estimates (available at http://www.bls.gov/oes/current/oes_nat.htm) (May 2023). We doubled these figures to account for benefits and overhead, and calculated the costs as follows:

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	40,215	$169.68	$6,823,681.20
Paralegal	40,215	$63.90	$2,569,738.50
Total			$9,393,419.70

We therefore estimate a total annualized cost burden of $9,393,420 (rounded to the nearest dollar).

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

For requests for CLIA categorization, the operating and maintenance cost, not including personnel, is estimated at $5 per submission (5 x 430), totaling $2,150. This includes the cost of copying and mailing copies of package inserts and a cover letter. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (e.g., paper).

For CLIA waiver applications, the total operating and maintenance cost is estimated at $540,000. This cost is largely attributed to clinical study costs, which include site selection and qualification, protocol review, and study execution (initiation, monitoring, closeout, and clinical site/subject compensation—including specimen collection for study as well as shipping and supplies).

14. Annualized Cost to the Federal Government

We estimate an average allocation of 5 full time equivalents (FTEs) to the review and processing of CLIA categorization requests submitted separately from marketing submissions and an average of 6 full time equivalents (FTEs) reviewing and processing waiver applications. Assuming a cost of $364,545 per position (which is the agency's projected average cost of an FTE including benefits*), we estimate an annual cost to the Federal government of $4,009,995 ($364,545 x 11 FTEs).

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2024 as provided by agency economists.

15. Explanation for Program Changes or Adjustments

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.

During the last renewal, the guidance document was unintentionally removed from ROCIS. We are now adding it back to address that oversight.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA posts CLIA test complexity categorizations on its website (available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm*) and updated weekly.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with these guidance documents and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on each guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.