CLIA Waiver Applications

0910-0598
SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Abstract:
The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires that clinical laboratories obtain a certificate from the Secretary of Health and Human Services (the Secretary) before accepting materials derived from the human body for laboratory tests (42 CFR 493.1) (http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol5/pdf/CFR-2011-title42-vol5-part493.pdf).

Laboratories that perform only tests that are "so simple and accurate as to render the likelihood of erroneous results negligible" may obtain a certificate of waiver (42 CFR 493.15(a) and (b)) (see above link). In the Federal Register of April 27, 2004 (69 FR 22849), the Secretary delegated to FDA the authority, under section 353 of the Public Health Service Act (42 U.S.C. 263a), as amended, to determine under CLIA whether particular tests (waived tests) are "simple" and have "an insignificant risk of an erroneous result" (http://www.gpo.gov/fdsys/pkg/FR-2004-04-27/pdf/04-9527.pdf).

On January 30 2008, FDA published a guidance document entitled "Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm079632.htm). This guidance document 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.

FDA is requesting approval of the following information collections:

CLIA waiver application (Reporting)
Manufacturers will prepare the CLIA waiver application, including study results, device description, hazard analysis information and labeling, and quick reference instructions.

CLIA waiver records (Recordkeeping)
Manufacturers will conduct studies to test the device proposed for waiver at external clinical sites representative of users to which the device will be marketed. Manufacturers will compare these results to those obtained by a reference (well-validated) method.

This information is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

FDA will use information from the information collection provisions to determine whether a particular test is "simple" and has "an insignificant risk of an erroneous result." FDA's evaluation of the test will determine whether FDA will categorize the device as CLIA waived.

Respondents 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

Manufacturers will have the option of submitting the waiver application or any part of the application electronically, whenever possible, although this was not addressed in the guidance document. Typically all manufacturers submit electronic copies in place of duplicate copies, and also submit electronically those sections of the application that contain data. These portions of the application account for approximately 50% of each application. In the past year, zero manufacturers submitted an application that was entirely electronic.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal agency responsible for the collection of information associated with the CLIA waiver application. The Secretary of Health and Human Services delegated this responsibility to FDA on April 27, 2004. No similar data is available from other sources.

5. Impact on Small Businesses or Other Small Entities

All respondents are businesses. Typically CLIA waiver applications are submitted by mid-sized (greater than 100 employees) or smaller companies. This information collection therefore has an impact on small entities. FDA aids small business in dealing with the recommendations for waiver application by providing guidance and information through the Center for Devices and Radiological Health's Division of Small Manufacturers, International, and Consumer Assistance. In addition to participating or conducting conferences, workshops, and seminars for small firms, DSMICA staff are available to respond to questions via a toll-free telephone number. Manufacturers may

also contact the Office of In Vitro Diagnostic Device Evaluation and Safety with questions.

6. Consequences of Collecting the Information Less Frequently

   The information collection is submitted no more than one time per device. CLIA waiver applications are submitted occasionally, specifically by manufacturers requesting CLIA waived categorization for a diagnostic test. There are no legal obstacles to reducing the burden.

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

   There are no special circumstances for this collection of information.

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

   In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of April 1, 2016 (81 FR 18858). We received no comments.

9. Explanation of Any Payment or Gift to Respondents

   No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

    Confidentiality of information submitted to FDA under a CLIA waiver submission is governed by the provisions of 21 CFR Part 20. However, FDA releases a decision summary of FDA's review of the submission as appropriate. These provisions do not permit disclosure of information that is trade secret or commercial confidential unless that information has been previously disclosed or as permitted under the Federal Freedom of Information Act. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. Information provided under this collection is handled in a manner to comply with the FDA regulations on public information in 21 CFR Part 20.

11. Justification for Sensitive Questions

    This collection of information does not include questions that are of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

    12 a. Annualized Hour Burden Estimate

    FDA estimates the burden of this collection as follows:

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
CLIA waiver application	40	1	40	1,200	48,000

Table 2.--Estimated Annual Recordkeeping Burden					
Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
CLIA waiver records	40	1	40	2,800	112,000

The total number of reporting and recordkeeping hours is 160,000 hours. FDA bases the burden on an Agency analysis of premarket submissions with clinical trials similar to the waived laboratory tests. Based on previous years' experience with CLIA waiver applications, FDA expects 40 manufacturers to submit one CLIA waiver application per year. The time required to prepare and submit a waiver application, including the time needed to assemble supporting data, averages 1,200 hours per waiver application for a total of 48,000 hours for reporting. Based on previous years experience with CLIA waiver applications, FDA expects that each manufacturer will spend 2,800 hours creating and maintaining the record for a total of 112,000 hours.

12b. Annualized Cost Burden Estimate

As noted above, the total number of reporting and recordkeeping hours is 160,000. Multiplying this by an average rate of $34 per hour* yields an estimated annual cost to respondents of $5,440,000. These rates are an estimate of an average of salaries of all individuals involved in the clinical study. This is tabulated below:

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Scientist	160,000	$34	$5,440,000

*Approximate hourly wage rate (rounded) is based on the Bureau of Labor and Statistics May 2015 National Occupational Employment and Wage Estimates for life, physical, and social science occupations (http://www.bls.gov/oes/current/oes_nat.htm).

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

The total operating and maintenance cost associated with the waiver application is estimated at $350,000. This cost is largely attributed to clinical study costs incurred, 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

FDA estimates that it spends an average of 6 full time equivalents (FTEs) reviewing and processing waiver applications. The cost of an average CDRH FTE in FY 2015 is $283,487 (which is the agency's projected average cost of an FTE including benefits*). Therefore, the expected annualized cost to the Federal government is approximately $1,700,922.

*Based on the Department of Health and Human Services, Fiscal Year 2015, Food and Drug Administration, Justification of Estimates for Appropriations Committees--ALL PURPOSE table (pp. 11-13).

15. Explanation for Program Changes or Adjustments

This is a request for extension without change of the information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish or tabulate the results of this information collection.

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

FDA is not seeking approval not to display the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.