SUPPORTING STATEMENT FOR
CLIA WAIVER APPLICATIONS

A. JUSTIFICATION

1. Need and Legal Basis

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires that clinical laboratories obtain a certificate from the Secretary of Health and Human Services before accepting materials derived from the human body for laboratory tests (42 CFR 493.1) (Attachment A).

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). (Attachment B). In the Federal Register of April 27, 2004 (69 FR 22849), the Secretary delegated to FDA the authority to determine under CLIA whether particular tests (waived tests) are "simple" and have "an insignificant risk of an erroneous result" (Attachment C).

Device manufacturers will submit to FDA an application for determination that a cleared or approved device meets this CLIA standard (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.

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.

2. Information Users

FDA will use information from the new 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 a manufacturer can obtain a certificate of waiver.

3. Improved Information Technology

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.

4. Duplication 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.

5. Small Businesses

This information collection will have a minimal impact on a substantial number of 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 is available to respond to questions via a toll-free telephone number. You may also contact the Office of In Vitro Diagnostic Device Evaluation and Safety.

6. Less Frequent Collection

This collection of information is collected only once per test. Without this collection of information, manufacturers could not receive a certificate of waiver.

7. Special Circumstances

This information collection is consistent with the guidelines prescribed in 5 CFR 1320.6.

8. Consultation Outside FDA

FDA consulted extensively with other agencies, including the Centers for Disease Control and Prevention (CDC) and the Center for Medicare and Medicaid Services (CMS), and incorporated their suggestions to the extent possible. CDC and CMS indicated overall agreement with the approach the guidance recommends.

Individuals consulted at CDC and CMS included:

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Many aspects of the guidance were based on recommendations proposed by the Clinical Laboratory Improvement Advisory Committee (CLIAC) waiver workgroup, February 2004. Participants of this workgroup included physicians, clinical laboratory professionals, manufacturers, public health laboratory professionals, and government agency representatives. Comments on the guidance were not solicited from industry or laboratory professionals prior to issuing the draft guidance document. FDA expects that these groups will send comments to the docket for the draft guidance issued September 2005.

In the Federal Register of September 7, 2005 (70 FR 53231) FDA solicited comments on the collection of information. No comments were received.

9. Payment/Gift to Respondent

No payment or gift is provided to respondents.

10. Confidentiality of Information

FDA treats all information related to CLIA applications as confidential. Confidentiality is not addressed in the guidance document.

11. Sensitive Questions

A CLIA waiver application does not include questions pertaining to sexual behavior, attitude, religious beliefs, or to other matters commonly considered private or sensitive in nature.

12. Burden Estimate (Total Hours and Wages)

The respondents to this collection of information are manufacturers of in vitro diagnostic devices.

FDA estimates the burden of this collection as follows:

TABLE 1. – ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours	Operating and Maintenance Costs
40	1	40	780	31,200	$5,500

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

TABLE 2. – ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours	Operating and Maintenance Costs
40	1	40	2,800	112,000	$60,700

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

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 780 hours per waiver application for a total of 31,200 hours for reporting. (40 manufacturers x 780 hours/waiver = 31,200 reporting hours)

FDA estimates that the recordkeeping burden per respondent is 2,800 hours. The number of hours (2,800) x the number of respondents (40) results in a total burden of 112,000 recordkeeping hours. FDA based the reporting and recordkeeping burden on an agency analysis of premarket submissions with clinical trials similar to the waived laboratory tests.

The total number of reporting and recordkeeping hours is 143,200 hours (31,200 hrs. + 112,000 = 143,200 hrs). Multiplying the total hours (143,000) by an average rate of $38 per hour yields an estimated annual cost to respondents of $5,441,600. These rates are an estimate of an average of salaries of all individuals involved in the clinical study. They are based on FDA's experience with industry, advertised employment notices, and trade salary surveys.

13. Estimates of Other Total Cost Burden to Respondents

The total operating and maintenance cost associated with the waiver application is estimated at $66,200. The cost consists of specimen collection for the clinical study (estimated $23,500); laboratory supplies, reference testing and study oversight (estimated $26,700); shipping and office supplies (estimated $6,000); and educational materials, including quick reference instructions (estimated $10,000). $23,500 + $26,700 + $6,000 + $10,000 = $66,200.

TOTAL COST

$5,441,600 (reporting & recordkeeping) + $66,200 (operating and maintenance) = $5,507,800 total cost.

There are no capital costs associated with this collection.

14. Cost to Federal Government

FDA estimates that it spends an average of 6 full time equivalents (FTEs) reviewing and processing waiver applications. An average full time equivalent employee is projected to cost FDA $113,800, which consists of the employee's salary and overhead. The burden imposed upon the government for this information collection is $682,800.

15. Program or Burden Changes

This is a new information collection.

16. Publication and Tabulation Dates

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

17. Display of OMB Approval Date

FDA is not requesting an exemption for display of the OMB expiration date.

18. Exception to Certification for Paperwork Reduction Act Submissions

FDA is not requesting an exemption to Certification for the Paperwork Reduction Act Submissions.

ATTACHMENTS

1.	Attachment A	42 CFR 493.1(a) and (b)	CLIA certificate requirement for laboratories
2.	Attachment B	42 CFR 493.15	Laboratories eligible for certificate of waiver
3.	Attachment C	69 FR 22849	FDA authority for waived tests