SUPPORTING STATEMENT FOR
ADMINISTRATIVE PROCEDURES
FOR
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) OF 1998
CATEGORIZATION

A. JUSTIFICATION

1. Need and Legal Basis

On February 28, 1992, the Department of Health and Human Services (DHHS) published the final laboratory standards regulations (57 FR 7002) implementing CLIA (Clinical Laboratory Improvement Amendments, codified at 42 CFR part §493). CLIA expands regulation of laboratory testing and calls for minimum requirements to help ensure the accuracy of tests, assays, or examinations of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or the impairment of, or assessment of the health of human beings. CLIA regulations describe three levels of test complexity: waived tests, moderate complexity tests, and high complexity tests

Laboratories performing only waived tests are subject to minimal regulation. Laboratories performing moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

On January 31, 2000, the responsibility for categorization of commercially marketed *in vitro* diagnostic (IVD) tests was transferred from the Centers for Disease Control and Prevention (CDC) to the Food and Drug Administration (FDA). This allows manufacturers to submit premarket notifications or applications for products and requests for complexity categorization of these products under CLIA to one agency.

The guidance document describes general administrative procedures FDA will use to assign a device's complexity category under CLIA regulations (42 CFR 493.17).

Reporting – Typically determination of CLIA complexity by FDA is performed at the time of premarket review, so that no additional reporting is needed. However, there are some cases when manufacturer's may request CLIA categorization when a premarket review is not needed (for example, devices exempt from premarket notification). In these cases, FDA recommends that manufacturers submit to FDA a brief description of why CLIA categorization is requested (e.g., exempt form 510(k), name change for a previously cleared device), the name of the device, the package insert (instructions for use), the product code, and regulation number.

2. Information Users

FDA will use information from the new information collection provisions to determine device complexity, and to post this information in the database for use by the public, including laboratories, and regulatory agencies.

3. Improved Information Technology

In the future, manufacturers may have the option of submitting the information electronically.

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 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. Manufacturers may also contact Office of In Vitro Diagnostic Devices (OIVD) concerning questions about administrative aspects of CLIA categorization.

6. Less Frequent Collection

This collection of information is collected only once per test, and only in cases where the categorization was not assigned during premarket review. Without this collection of information, FDA would not be able to inform manufacturers of the CLIA complexity categorizations for these tests and would not be able to post CLIA complexity categorizations for the public.

7. Special Circumstances

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

8. Consultation Outside FDA

On Wednesday, February 14, 2007 (72 FR 7043), FDA solicited comments on these information collections. 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 of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Operating and Maintenance Costs
42 CFR 493.17	60	15	900	1 hr	900 hr	$45,000

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

The number of respondents is approximately 60. On average, each respondent will request categorizations (independent of a 510(k) or PMA) 15 times per year.

Costs to Repondents

FDA estimates that industry as a whole (estimated at 60 respondents) will spend approximately 0.5 FTEs to submit the CLIA categorization requests that are separate from 510(k) or PMA submissions. FDA estimates that less than 0.5 FTE costs a total of approximately $70,000, which consists of the employee's salary and overhead.

13. Estimates of Other Total Cost Burden to Respondents

The hourly cost, not including personnel is estimated at $50 for a total operating and maintenance cost of $45,000. This includes the cost of copying and mailing copies of package inserts, and a

cover letter including a statement of the reason for the request, and reference to the original 510(k) numbers, including regulation numbers and product codes. There are no capital costs associated with this collection of information.

14. Cost to Federal Government

FDA estimates that it spends an average of 3 full time equivalents (FTEs) reviewing and processing CLIA categorization requests submitted separately from 510(k) or PMA submissions. 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 $341,400.

15. Program or Burden Changes

This is a new information collection.

16. Publication and Tabulation Dates

FDA posts CLIA test complexity categorizations on its website, updated monthly..

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.