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

**0910-0607**

**SUPPORTING STATEMENT**

## A. Justification

1. Circumstances Making the Collection of Information Necessary

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 §493.17, http://edocket.access.gpo.gov/cfr_2009/octqtr/pdf/42cfr493.17.pdf, 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).

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 manufacturers 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.

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 the information collected to determine device complexity, and to post this information in the database for use by the public, including laboratories, and regulatory agencies.

The respondents for this information collection are private sector, for-profit device manufacturers requesting CLIA categorization in cases where a device does not require a premarket notification review.

3. Use of Improved Information Technology and Burden Reduction

At this time approximately 100% of respondents submit the original CLIA categorization request as hard copy. In cases where minor changes are needed after review by FDA (estimated as 10-20% of cases), respondents submit changes via email. In the future, manufacturers may have the option of submitting the original information electronically as well.

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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.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that approximately 50% of CLIA categorization requests are from small businesses this information collection will have a minimal impact on small businesses. 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 (DMISCA). 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. Consequences of Collecting the Information Less Frequently

This collection of information is collected occasionally. It is collected once per test system 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. There are no legal obstacles to reduce 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, FDA published a 60- day notice for public comment in the FEDERAL REGISTER of May 4, 2010 (75 FR 23781). There were 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

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

11. Justification for 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. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates that approximately 60 respondents (manufacturers) will respond 15 times per year, with a total of one hour spent on each response. The estimated burden hours are therefore estimated as approximately 900 hours per year. This estimate is based on FDA's experience regarding the information that manufacturers submit for this type of collection.

Estimated Annual Reporting Burden1

| Activity | No. of Respondents | Annual Frequency per Response | Total Annual Respondents | Hours per Response | Total Hours | Operating and Maintenance Costs |
|---|---|---|---|---|---|---|
| Preparation and submission of cover page and manufacturer's current copy of device labeling. | 60 | 15 | 900 | 1 | 900 | $46,800 |

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

12b. Annualized Cost Burden Estimate

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 $73,800 which consists of the employee's salary and overhead.

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|
| Regulatory Affairs Specialist | 900 | $82.00 | $73,800 |

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

The operating and maintenance costs, not including personnel, is estimated at $52 per submission with a total operating and maintenance cost of $46, 800. 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.

14. Annualized Cost to the 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. Explanation for Program Changes or Adjustments

There was no increase to the burden hours from the last submission. The operating and maintenance costs have increased by $1800.00 due to inflation.

16. Plans for Tabulation and Publication and Project Time Schedule

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

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

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