Requests for CLIA Categorization

0910-0607

SUPPORTING STATEMENT

Terms of Clearance: None.

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 the Clinical Laboratory Improvement Amendments (CLIA), 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, "Guidance for Industry and FDA Staff: Administrative Procedures for CLIA Categorization," 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.

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

Though manufacturers must submit the original CLIA categorization request in paper, they also have the option of submitting an electronic copy. Approximately 95% of respondents submit an electronic copy of the request. In cases where minor changes are needed after review by FDA (estimated as 10-20% of cases), respondents submit changes via email.

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 categorization request. 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 percent of CLIA categorization requests are from 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 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(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of May 22, 2013 (78 FR 30312). No comments were received.

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 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.

Under the Freedom of Information Act (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). One such provision, 5 U.S.C. 552(b)(4), exempts "trade secrets and commercial or financial information that is privileged or confidential" from the requirement of public disclosure. Section 520(c) of the FD&C Act prohibits FDA from disclosing any information exempted from public disclosure under 5 U.S.C. 552(b)(4). Part 20 of FDA's regulations (21 CFR part 20), sets forth FDA's general policy concerning public availability of FDA records.

11. Justification for Sensitive Questions

The information collection 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

12a. Annualized Hour Burden Estimate

FDA estimates that approximately 60 respondents (manufacturers) will respond 15 times per year, with a total of 1 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.

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Request for CLIA categorization	60	15	900	1	900

12b. Annualized Cost Burden Estimate

We expect that the information collection will be satisfied by regulatory affairs specialists. We have updated the hourly wage rate estimates for regulatory affairs specialists (previously estimated as $82). This resulted in a reduction of the estimated respondent costs.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Specialist*	900	$45.46	$40,914

*The estimated wage rate for a Regulatory Affairs Professional was derived from an average of the annual wage rates listed in several sources including Salary.com, eHow.com, MDDIonline.com, and Recruiter.com. The hourly wage rate assumes a 40-hour work week.

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 (FTE) employee is projected to cost FDA/CDRH $209,632,* which consists of the employee's salary and any overhead which accompanies that employee. The burden imposed upon the government for this information collection is, therefore, approximately $628,896.

*Based on the FY 2012 President's Budget Request All Purpose Table – Total Program Level table.

15. Explanation for Program Changes or Adjustments

We revised the title of the information collection for clarity.

There are no program changes or adjustments associated with this request for extension of the information collection.

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 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.