U.S. Food and Drug Administration
Administrative Procedures for CLIA Categorization
OMB Control Number 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 of 1988 (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.

The 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, "Administrative Procedures for CLIA Categorization," describes general administrative procedures FDA will use to assign a device's complexity category under the 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 from 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.

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 Industry and Consumer Education (DICE). In addition to participating or conducting conferences, workshops, and seminars for small firms, DICE staff are 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 June 26, 2019 (84 FR 30127). 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

This ICR Collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g. point of contact). The PII submitted is name, work address, work email address, work telephone number and occasionally work fax number.

FDA further determined that although PII is collected the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of the individuals.

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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 the number of respondents is approximately 80. On average, each respondent requests such categorizations 5 times per year, with a total of 1 hour spent on

each response. The estimated burden hours are therefore 400 hours per year. This estimate is based on FDA's experience regarding the information that manufacturers submit for this type of collection and on recent receipt data for requests for CLIA categorization separate from a product application.

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	80	5	400	1	400

12b. Annualized Cost Burden Estimate

We expect that the information collection will be satisfied by regulatory affairs professionals.*

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Professional	400	$72	$28,800

* The estimated wage rate for a Regulatory Affairs Professional is based on The Regulatory Affairs Professional Society (RAPS) average total annual compensation of $150,422 for a U.S. regulatory affairs professional (https://www.raps.org/getattachment/Careers/Scope-of-Practice-Survey/2016-Scope-of-Practice-Compensation-Report-for-the-Regulatory-Profession.pdf.aspx?lang=en-US, p. 11, accessed 10/26/18). The hourly wage rate of $72 assumes a 40-hour work week and is rounded to the nearest dollar..

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

The operating and maintenance cost, not including personnel, is estimated at $5 per submission (5 x 400), totaling $2,000. This includes the cost of copying and mailing copies of package inserts and a cover letter. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (e.g., paper).

Upon review of this information collection, we have adjusted the estimated cost per submission (previously $52). Because the submissions are typically only a few pages per package insert and copying or printing and postage for a few pages is not expected to be more than $5, we believe this is a more appropriate cost burden estimate.

14. Annualized Cost to the Federal Government

FDA estimates that it spends an average of 5 full time equivalents (FTEs) reviewing and processing CLIA categorization requests submitted separately from marketing submissions. Based on a cost of $270,305 per position (which is the agency's projected average cost of an FTE including benefits*), the estimated annual Federal cost is $1,351,525.

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2018, as provided by agency economists.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall decrease of 500 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years. Also, upon review of this information collection, we believe the previous estimate may have included requests for categorization associated with a premarket submission, the burden estimate of which is included under the OMB approval for the applicable premarket submission. We have therefore revised the number of respondents/responses to include only those that are separate from a product application, consistent with the scope of this 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 will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.