4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0031]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Clinical Laboratory Improvement Amendments Act of 1988 Waiver Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0598. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

CLIA Waiver Applications--

OMB Control Number 0910-0598--Extension

Congress passed the CLIA (Pub. L. 100-578) in 1988 to establish quality standards for all laboratory testing. The purpose was to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test took place. CLIA requires that clinical laboratories obtain a certificate from the Secretary of Health and Human Services (the Secretary), before accepting materials derived from the human body for laboratory tests (42 U.S.C. 263a(b)). Laboratories that perform only tests that are "simple" and that have an "insignificant risk of an erroneous result" may obtain a certificate of waiver (42 U.S.C. 263a(d)(2)). The Secretary has delegated to FDA the authority to determine whether particular tests (waived tests) are "simple" and have "an insignificant risk of an erroneous result" under CLIA (69 FR 22849, April 27, 2004).

On January 30, 2008, FDA published a guidance document entitled "Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm079632.htm). This guidance document describes recommendations for device manufacturers submitting to FDA an application for determination that a cleared or approved device meets this CLIA standard (CLIA waiver application). The guidance recommends that CLIA waiver applications include a description of the features of the device that make it "simple"; a report describing a hazard analysis that identifies potential sources of error, including a summary of the design and results of flex studies and conclusions drawn from the flex studies; a description of

fail-safe and failure alert mechanisms and a description of the studies validating these mechanisms; a description of clinical tests that demonstrate the accuracy of the test in the hands of intended operators; and statistical analyses of clinical study results.

In the **Federal Register** of April 1, 2016 (81 FR 18858), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Total Operating and Maintenance Costs
CLIA waiver application	40	1	40	1,200	48,000	$350,000

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

Table 2.--Estimated Annual Recordkeeping Burden[1]

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
CLIA waiver records	40	1	40	2,800	112,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The total number of reporting and recordkeeping hours is 160,000 hours. FDA bases the burden on an Agency analysis of premarket submissions with clinical trials similar to the waived laboratory tests. 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 1,200 hours per waiver application for a total of 48,000 hours for reporting. Based on previous years' experience with CLIA waiver applications, FDA expects that each manufacturer will spend 2,800 hours creating and maintaining the record for a total of 112,000 hours.

The total operating and maintenance cost associated with the waiver application is estimated at $350,000. This cost is largely attributed to clinical study costs incurred, which include site selection and qualification, protocol review, and study execution (initiation, monitoring, closeout, and clinical site/subject compensation--including specimen collection for study as well as shipping and supplies).

Dated: July 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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