

employees in ORR with access to the database, and a limited number of employees in other HHS offices, *e.g.*, CDC and SAMHSA, receiving data from ORR) who are advised of the confidentiality of the records and the civil and criminal penalties for misuse. Personnel with authorized access to the system are provided privacy and security training for electronically stored information. The records are processed and stored in a secure environment. All records are stored in an area that is physically safe from access by unauthorized persons at all times. Safeguards conform to the HHS Information Security Program, <http://www.hhs.gov/ocio/securityprivacy/index.html>.

#### RETENTION AND DISPOSAL:

The records will be retained indefinitely pending scheduling with the National Archives and Records Administration (NARA). Because the records will have continuing value for epidemiological purposes, the retention period proposed to NARA may be 100 years or longer.

#### SYSTEM MANAGER AND ADDRESS:

Director, Division of Refugee Health, Office of Refugee Resettlement, Administration for Children and Families, Mary E. Switzer Building, 330 C Street SW., Washington, DC 20201.

#### NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should address written inquiries to the System Manager. The request should include the alien number, age, telephone number, and/or email address of the individual data subject. The request must be signed by the requester. Verification of identity as described in the Department's Privacy Act regulations may be required (see 45 CFR 5b.5). If the individual data subject is a minor or is legally incompetent, the individual's legal representative (parent or court-appointed guardian) may request notification on the individual's behalf. The representative must provide verification of identity and competent evidence of the parent or guardian relationship.

#### RECORD ACCESS PROCEDURES:

Individuals seeking access to a record about them in this system of records should address written inquiries to the System Manager. The request should include the alien number, age, telephone number, and/or email address of the individual. The request must be signed by the individual to whom such

information pertains. Verification of identity as described in the Department's Privacy Act regulations may be required (see 45 CFR 5b.5). If the individual data subject is a minor or is legally incompetent, the individual's legal representative (parent or court-appointed guardian) may request access on the individual's behalf. The representative must provide verification of identity and competent evidence of the parent or guardian relationship.

#### CONTESTING RECORD PROCEDURES:

Individuals seeking to amend a record about them in this system of records should address the request for amendment to the System Manager. The request should:

- Include the alien number, age, telephone number, and/or email address of the individual, and should be signed by the individual to whom such information pertains;
- identify the system of records that the individual believes includes his or her records or otherwise provide enough information to enable the identification of the individual's record;
- identify the information that the individual believes is not accurate, relevant, timely or complete;
- indicate what corrective action is sought; and
- include supporting justification or documentation for the requested amendment.

Verification of identity as described in the Department's Privacy Act regulations may be required (see 45 CFR 5b.5). If the individual data subject is a minor or is legally incompetent, the individual's legal representative (parent or court-appointed guardian) may make an amendment request on the individual's behalf. The representative must provide verification of identity and competent evidence of the parent or guardian relationship.

#### RECORD SOURCE CATEGORIES:

The information maintained in the system is provided by states and other resettlement organizations when they report a suicide attempt using the Refugee Suicide and Report Form. The State Refugee Coordinator and State Refugee Health Coordinator will be primarily responsible for reporting this information. They will collect the information from various sources within the state including refugee resettlement agencies, public health departments, ethnic-based community organizations, and refugee community leaders.

#### EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

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## 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 August 17, 2016.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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 <sup>1</sup>

Activity	Number of respondents	Number 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

<sup>1</sup> There are no capital costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
CLIA waiver records .....	40	1	40	2,800	112,000

<sup>1</sup> 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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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2016–N–0001]

**Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Public Workshop**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the following public workshop entitled “Refurbishing, Reconditioning, Rebuilding, Remarketing,

Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers.” The topics to be discussed are the current regulatory environment for these activities, the definitions of the various terms FDA proposed in the prior **Federal Register** notice on this subject, and whether these activities should appropriately be regulated by FDA or a non-governmental organization.

**DATES:** The public workshop will be held on October 27, 2016, from 8:30 a.m. to 5 p.m. and October 28, 2016, from 8:30 a.m. to 4 p.m.

**ADDRESSES:** The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.