waiver application is estimated at $66,200. The cost consists of specimen collection for the clinical study (estimated $23,500); laboratory supplies, reference testing and study oversight (estimated $26,700); shipping and office supplies (estimated $6,000); and educational materials, including quick reference instructions (estimated $10,000).

In the **Federal Register** of September 14, 2012 (77 FR 56846), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one PRA-related comment.

The comment asserts that the amount of time per response and the cost associated with a waiver application are underestimated. FDA has revised its estimates based on the comment received on the 60-day **Federal Register** notice. As shown below, FDA is increasing the hours per response from 780 to 1,200 hours. FDA is also increasing the estimated operating and maintenance cost burden from $66,200 to $350,000.

The Center for Devices and Radiological Health (including both the Office of In Vitro Diagnostics and the Division of Biostatistics) maintains dialogue with industry representatives (the Advanced Medical Technology Association), regarding development of additional options regarding study design and data analysis approaches for certain devices to demonstrate they are suitable candidates for waiver.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

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

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

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

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

Dated: April 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–09180 Filed 4–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0324]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry, FDA Staff, and Foreign Governments: Fiscal Year 2012 Medical Device User Fee Small Business Qualification and Certification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry, FDA Staff, and Foreign Governments: Fiscal Year 2012 Medical Device User Fee Small Business Qualification and Certification'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On January 31, 2013, the Agency submitted a proposed collection of information entitled ''Guidance for Industry, FDA Staff, and Foreign Governments: Fiscal Year 2012 Medical Device User Fee Small Business Qualification and Certification'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0508. The approval expires on March 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: April 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–09181 Filed 4–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0114]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Electronic Submission of Medical Device Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Electronic Submission of Medical Device Registration and Listing'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On August 06, 2012, the Agency submitted a proposed collection of information entitled ''Electronic Submission of Medical Device Registration and Listing'' to OMB for review and

clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0625. The approval expires on March 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: April 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–09182 Filed 4–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

ACTION: Notice

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: Evaluating the Impact of 1115 Medicaid Waivers on Ryan White HIV/AIDS Program and Its Clients and Providers (OMB No. 0915–xxxx)—New

Abstract: Section 1115 of the Social Security Act allows states to develop, test, and implement new approaches to providing Medicaid coverage outside of federal program rules. Leading up to full implementation of the Affordable Care Act, states have begun to use Section 1115 Medicaid demonstration waivers as a ''bridge'' to 2014. This project will examine 1115 Medicaid waivers that have expanded eligibility to specifically include people living with HIV/AIDS (PLWH) who are not otherwise eligible for Medicaid services. Since 1990, the Ryan White HIV/AIDS Program (RWHAP) has provided funding for primary care, medications, and support services for PLWH, helping fill the health care and service gap for those who are uninsured or ineligible for Medicaid. Given the important role of the RWHAP and Medicaid in meeting the health care needs of PLWH, there is a need to better understand how Medicaid expansion and the 1115 Medicaid waivers will affect the RWHAP and how the waivers have prepared states for implementation of the Affordable Care Act.

As part of this project, case studies will be conducted in eight states that have implemented 1115 Medicaid waivers to expand Medicaid eligibility for PLWH. The case studies will include site visits and discussions with the state Medicaid programs and with RWHAP grantees and service providers to examine the waivers and their impact on PLWH. In addition, the studies will explore whether and how the 1115 Medicaid waivers have helped states and RWHAP grantees and providers prepare for implementation of the Affordable Care Act, including providing insights into Medicaid expansion. Data will be collected through qualitative interviews, guided by discussion tools with questions tailored for four specific groups of individuals from: (1) State Medicaid Agencies; (2) Ryan White HIV/AIDS Program Part B grantees and service providers; (3) Ryan White HIV/AIDS Program Part A grantees and service providers; and (4) Ryan White HIV/AIDS Program Part C grantees and clinical providers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Qualitative Interview Data Collection Tool—State Medicaid Agencies	40	1	40	2	80
Qualitative Interview Data Collection Tool—RWHAP Part A Administrators/Planning Councils	80	1	80	2	160
Qualitative Interview Data Collection Tool—RWHAP Part B/ADAP Directors and Coordinators	80	1	80	2	160
Qualitative Interview Data Collection Tool—RWHAP Part C Grantees/Clinical Providers	80	1	80	2	160
Total	280	.....	280	.....	560