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]

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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