DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0018]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Health Care Professional Survey of Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Health Care Professional Survey of Prescription Drug Promotion'' 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 October 12, 2012, the Agency submitted a proposed collection of information entitled ''Health Care Professional Survey of Prescription Drug Promotion'' 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 0910–0730. The approval expires on February 29, 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. 2013–09176 Filed 4–18–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0937]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Clinical Laboratory Improvement Amendments 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 May 20, 2013.

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

Clinical Laboratory Improvement Amendments Waiver Applications—(OMB Control Number 0910–0598)—Extension

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) (Public Law 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.

The total number of reporting and recordkeeping hours is 143,200 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 780 hours per waiver application for a total of 31,200 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 $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]

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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