performing the following: (1) Plans, directs, and conducts assistance management activities for CDC through the awards of grants and cooperative agreements (competitive and non-competitive) across the public health system; (2) plans, directs, coordinates, and conducts the grants managements functions and processes in support of public health assistance awards; (3) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC; (4) provides leadership, direction, and approaches in developing grants announcements; (5) participates with leadership in program planning, policy determination, evaluation, and directions concerning assistance strategies and execution; (6) provides leadership and guidance to CDC project officers and public health program officials related to grants activities; (7) maintains a close working relationship with CDC program office components in carrying out their public health missions; (8) reviews assistance applications from a management point of view for conformity to laws, regulations, and policies and alignment to CDC's public health goals, and issues grants and cooperative agreements; (9) provides continuing surveillance of financial and administrative aspects of assistance-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public health activities; (10) gives technical assistance, where indicated, to improve the management of assistance-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC office and the public; (11) assures that grantee performance is in accordance with assistance requirements; (12) provides for the collection and reporting of business management and public health programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (13) maintains branch's official assistance files; and (14) provides innovative problem-solving methods in the coordination of international grants for a wide range plan with public health partners in virtually all major domestic and international health agencies dealing with health priorities/issues, to include resolution of matters with the Department of State.

Dated: May 10, 2013.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2013–12044 Filed 5–21–13; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0514]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requests for Clinical Laboratory Improvement Amendments Categorization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requests for Clinical Laboratory Improvement Amendments of 1998 (CLIA) categorization of in vitro diagnostic (IVD) tests when a premarket review is not needed.

DATES: Submit either electronic or written comments on the collection of information by July 22, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Requests for CLIA Categorization—42 CFR 493.17 (OMB Control Number 0910–0607)—Extension

A guidance document entitled ''Guidance for Administrative Procedures for CLIA Categorization'' was released on May 7, 2008. The document describes procedures FDA uses to assign the complexity category to a device. Typically, FDA assigns complexity categorizations to devices at the time of clearance or approval of the device. In this way, no additional burden is incurred by the manufacturer because the labeling (including operating instructions) is included in the premarket notification (510(k)) or premarket approval application (PMA). In some cases, however, a manufacturer may request CLIA categorization even if FDA is not simultaneously reviewing a 510(k) or PMA. One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (e.g. name change, exempt from 510(k) review). The guidance recommends that in the

correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available.

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	Operating and maintenance costs
Request for CLIA categorization	60	15	900	1	900	$46,800

The number of respondents is approximately 60. On average, each respondent will request categorizations (independent of a 510(k) or PMA) 15 times per year. The cost, not including personnel, is estimated at $52 per hour ($52 \times 900$), totaling $46,800. This includes the cost of copying and mailing copies of package inserts and a cover letter, which includes a statement of the reason for the request and reference to the original 510(k) numbers, including regulation numbers and product codes. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (e.g. paper).

Dated: May 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–12099 Filed 5–21–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0502]

Standardizing and Evaluating Risk Evaluation and Mitigation Strategies; Notice of Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a 2-day public meeting to obtain input on issues and challenges associated with the standardization and assessment of risk evaluation and mitigation strategies (REMS) for drug and biological products. As part of the reauthorization of the Prescription Drug User Fee Act (PDUFA), FDA has committed to standardizing REMS to better integrate them into, and reduce their burden to, the existing and evolving health care system. As part of the PDUFA commitments, FDA will also seek to develop evidence-based methodologies for assessing the effectiveness of REMS.

To obtain input from stakeholders about REMS standardization and evaluation, FDA will hold a public meeting to give stakeholders, including health care providers, prescribers, patients, pharmacists, distributors, drug manufacturers, vendors, researchers, standards development organizations, and the public an opportunity to provide input on ways to standardize and assess REMS.

DATES: The meeting will be held on July 25 and 26, 2013, from 8:30 a.m. to 4:30 p.m. Individuals who wish to present at the meeting must register by July 10, 2013. See section IV of this document for information on how to register to speak at the meeting.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify each set of comments with the corresponding docket number for the public meeting as follows: ''Docket No. FDA–2013–N–0502, ''Standardization and Evaluation of Risk Evaluation and Mitigation Strategies, Public Meeting.''

FOR FURTHER INFORMATION CONTACT: Adam Kroetsch, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993, 301–796–3842, FAX: 301–847–8443, email: *REMS_Standardization@fda.hhs.gov.*

I. Background

This meeting builds upon prior stakeholder feedback on and input into the design, implementation, and assessment of REMS. In July 2010, FDA held a public meeting to obtain input on issues associated with the development and implementation of REMS. In June 2012, FDA held a public workshop to discuss survey methodologies and instruments that can be used to evaluate patients' and health care providers' knowledge about the risks of drugs marketed with an approved REMS. In addition, the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) requires FDA to bring, at least annually, one or more drugs with REMS with elements to assure safe use (ETASU) before the Drug Safety and Risk Management Advisory Committee. FDA also regularly discusses both pre- and postapproval REMS with ETASUs with various FDA advisory committees in the context of specific applications.

This meeting also builds on FDA's internal efforts to improve the design, implementation and assessment of REMS. In 2011, FDA created the REMS Integration Initiative, designed to evaluate and improve its implementation of REMS authorities. More information about the REMS Integration Initiative can be found at (*http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm350852.htm*). As part of this effort, FDA seeks to improve future REMS assessments and incorporate the latest methodologies in the evolving science of risk management. In its February 2013 report, ''FDA Lacks Comprehensive Data to Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety,'' the Department of Health and Human Services Office of the Inspector General affirmed the need to identify and implement reliable methods to assess the effectiveness of REMS and REMS components. This report is available at *https://oig.hhs.gov/oei/reports/oei-04-11-00510.pdf.*

This public meeting is intended to meet performance goals included in the fifth reauthorization of the Prescription Drug User Fee Act (PDUFA V). This reauthorization, part of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) signed by the President on July 9, 2012, includes a number of performance goals and procedures that are documented in the PDUFA V