ADDRESSES: The webcast will be broadcast from the Centers for Disease Control and Prevention facility, 1600 Clifton Rd. NE., Atlanta, GA 30329.

FOR FURTHER INFORMATION CONTACT:

CDC: LCDR. Jacinta Smith, Division of Select Agents and Toxins, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS A–46, Atlanta, GA 30333; *lrsat@cdc.gov*.

APHIS: Dr. Lidia Carrera, APHIS Select Agent Program, APHIS, 4700 River Road, Unit 2, Riverdale, MD 20737; *Lidia.Carrera@aphis.usda.gov*

SUPPLEMENTARY INFORMATION: Title II of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, ''Enhancing Controls on Dangerous Biological Agents and Toxins'' (sections 201 through 231), provides for the regulation of certain biological agents and toxins by the Department of Health and Human Services (subtitle A, sections 201–204) and the Department of Agriculture (subtitle B, sections 211–213). Additionally, the statute provides for interagency coordination between the two departments regarding overlap agents and toxins (subtitle C, section 221). For the Department of Health and Human Services(HHS), the Centers for Disease Control and Prevention (CDC) oversees entities that possess, use or transfer select agents and toxins that have the potential to pose a severe threat to public health and safety. The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) has a parallel program that oversees entities that possess, use or transfer select agents that have the potential to pose a severe threat to animal or plant health, or to animal or plant products . These two programs constitute the Federal Select Agent Program. The Federal Bureau of Investigation's (FBI) Criminal Justice Information Services conducts security risk assessments of (1) all individuals and nongovernmental entities that request to possess, use, or transfer select agents and toxins, (2) all individuals who need access to select agents and toxins.

The webcast announced in this notice is an opportunity for the regulated community (i.e., registered entity responsible officials, alternate responsible officials, and entity owners) and other interested individuals to obtain specific regulatory guidance and information on standards concerning biosafety, biosecurity and incident response issues related to the Federal Select Agent Program. Representatives from HHS/CDC, USDA/APHIS, and the FBI will be present during the webcast to address questions and concerns from the web participants.

Updates on the changes to the select agent regulations; occupational health, information and physical security; personnel suitability; FD–961 form, and changes to the APHIS/CDC Form 1 are among the issues that will be discussed. A question and answer session will take place after each topic.

Registration instructions are found on the Federal Select Agent Program Web site *http://www.selectagents.gov*. Registration ends on October 16, 2012. This is a webcast only event and there will be no on-site participation at the HHS/CDC broadcast facility. Registration is required for participation. This is a 100% webcast; therefore, in person participation cannot be accommodated.

Participants will be able to submit questions during the webcast at *selectagentwkshp@cdc.gov*. Closed-captioning services will be provided during the webcast.

Dated: September 10, 2012.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2012–22653 Filed 9–13–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0937]

Agency Information Collection Activities; Proposed Collection; Comment Request; Clinical Laboratory Improvement Amendments of 1988 Waiver Applications

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 collections of information associated with Clinical Laboratory Improvement Amendments of 1988 waiver applications.

DATES: Submit either electronic or written comments on the collection of information by November 13, 2012.

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.

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

Congress passed the Clinical Laboratory Improvement Amendments (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.

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).

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	780	31,200	$66,200

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

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

Dated: August 30, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–22660 Filed 9–13–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0921]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal

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 the use of the FDA Electronic Submission Gateway (ESG) and the Safety Reporting Portal (the SRP) to collect adverse event reports and other