''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.

In the **Federal Register** of April 1, 2016 (81 FR 18858), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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.

The total number of reporting and recordkeeping hours is 160,000 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 1,200 hours per waiver application for a total of 48,000 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 $350,000. This cost is largely attributed to clinical study costs incurred, which include site selection and qualification, protocol review, and study execution (initiation, monitoring, closeout, and clinical site/subject compensation—including specimen collection for study as well as shipping and supplies).

Dated: July 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16886 Filed 7–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers.'' The topics to be discussed are the current regulatory environment for these activities, the definitions of the various terms FDA proposed in the prior **Federal Register** notice on this subject, and whether these activities should appropriately be regulated by FDA or a non-governmental organization.

DATES: The public workshop will be held on October 27, 2016, from 8:30 a.m. to 5 p.m. and October 28, 2016, from 8:30 a.m. to 4 p.m.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Felicia Brayboy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3464, Silver Spring, MD 20993, 301–796–8086, *Felicia.Brayboy@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On March 4, 2016, FDA published in the **Federal Register** a notice (81 FR 11477) requesting comments from interested persons, including those engaged or otherwise interested in the ''Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices,'' including radiation-emitting devices subject to the electronic product radiation control provisions of the Federal Food, Drug, and Cosmetic Act. FDA took this action, in part, because various stakeholders have expressed concerns about the quality, safety, and continued effectiveness of medical devices that have been subject to one or more of these activities. This docket asked that interested persons, including Original equipment manufacturers (OEMs), health care establishments, and third-party entities review proposed terms and definitions and provide edits if applicable. The docket also sought insights into basic concepts with regard to these activities. FDA is currently reviewing all of the comments and will use them to inform a set of working questions designed to promote an understanding of challenges and best practices to mitigate risks associated with these activities. These working questions will be addressed in group discussions on both days of the workshop.

II. Topics for Discussion at the Public Workshop

The public workshop sessions will incorporate the following general themes pertaining to the refurbishing, reconditioning, rebuilding, remarketing, remanufacturing, and servicing of medical devices:

- Establish working definitions for third-party and OEM activities.
- Discuss benefits and challenges that stakeholders encounter, potential benefits and risks to patients/users, and failure modes of devices introduced as a result of performing activities associated with third-party entities.
- Identify current best practices and discuss alternative methods to mitigate risks associated with performing activities associated with third-party entities.
- Determine whether specific procedures are necessary for each activity as it relates to third-party services performed.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by September 23, 2016, by 4 p.m. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop; will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Peggy Roney, Office of Communication, Education, and Radiation Programs, 301–796–5671, email: *Peggy.roney@fda.hhs.gov,* no later than October 13, 2016.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Peggy Roney to register (see special accomodations contact). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. The Webcast link will be available on the registration Web page after October 20, 2016. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Requests for Oral Presentations: This public workshop includes a public comment session and topic-focused sessions. During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments and participate in the focused sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by September 30, 2016. All requests to make oral presentations must be received by the close of registration on September 23, 2016, by 4 p.m. (EDT). If selected as a presenter, any presentation materials must be emailed to Felicia Brayboy (see **FOR FURTHER INFORMATION CONTACT**) no later than October 13, 2016. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

Dated: July 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16887 Filed 7–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the