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

provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Translational Research (R24) and Patient-Oriented Mentored Training (K23) Grant Applications.

Date: August 4, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, Tenleytown Ballroom II, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Anne E. Schaffner, Ph.D., Chief, Scientific Review Branch Division of Extramural Research, National Eye Institute, 5635 Fishers Lane, Suite 1300, MSC 9300, Bethesda, MD 20892–9300, (301) 451–2020, *aes@nei.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: July 12, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–16833 Filed 7–15–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Data and Information on Technologies Used To Identify Substances With the Potential To Cause Acute Systemic Toxicity

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests data and information on approaches and/or technologies currently used to identify substances with the potential to cause acute systemic toxicity when swallowed, inhaled, or absorbed through the skin. Submitted information will be used to assess the state of the science and determine technical needs for non-animal test methods used to evaluate the potential of chemicals to induce acute systemic toxicity.

DATES: *Receipt of information:* Deadline is September 1, 2016.

ADDRESSES: Data and information should be submitted electronically to *niceatm@niehs.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM; email: *warren.casey@nih.gov;* telephone: (919) 316–4729.

SUPPLEMENTARY INFORMATION:

Background: Acute systemic toxicity tests are conducted to determine the potential for a single or short-term dose of a substance to cause illness or death when inhaled (inhalation toxicity testing), swallowed (oral toxicity testing), or absorbed through the skin (dermal toxicity testing). These tests are required by multiple regulatory agencies and can use large numbers of animals. NICEATM, which fosters the evaluation and promotion of alternative test methods for regulatory use, supports efforts to develop, validate, and implement alternative approaches for acute systemic toxicity testing that replace, reduce, or refine use of animals in testing.

Request for Information: NICEATM requests data and information on approaches and/or technologies currently used to identify substances with the potential to cause acute systemic toxicity. Respondents should provide information on any activities relevant to the development or validation of alternatives to *in vivo* tests currently required by regulatory agencies that assess acute oral, dermal, or inhalation toxicity. Of specific interest are chemical-specific data from non-animal tests for acute systemic toxicity hazard, as well as available data on the same chemicals from *in vivo* acute systemic toxicity tests, such as ethical human or animal studies or accidental human exposures.

Respondents to this request for information should include their name, affiliation (if applicable), mailing address, telephone, email, and sponsoring organization (if any) with their communications. The deadline for receipt of the requested information is September 1, 2016. Responses to this notice will be posted at *http://ntp.niehs.nih.gov/go/iv-data.* Persons submitting responses will be identified on the Web page by name and affiliation or sponsoring organization, if applicable.

Responses to this request are voluntary. No proprietary, classified, confidential, or sensitive information should be included in responses. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

Background Information on NICEATM: NICEATM conducts data analyses, workshops, independent validation studies, and other activities to assess new, revised, and alternative test methods and strategies. NICEATM also provides support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) provides authority for ICCVAM and NICEATM in the development of alternative test methods. Information about NICEATM and ICCVAM is found at *http://ntp.niehs.nih.gov/go/niceatm* and *http://ntp.niehs.nih.gov/go/iccvam.*

Dated: July 12, 2016.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2016–16840 Filed 7–15–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Kidney Interagency Coordinating Committee Meeting

SUMMARY: The Kidney Interagency Coordinating Committee (KICC) will hold a meeting on September 19, 2016, on ''CRIC and CKiD: Using longitudinal CKD cohort study findings to plan population health interventions.'' The meeting is open to the public.

DATES: The meeting will be held on September 19, 2016, 9 a.m. to 12 p.m. Individuals wanting to present oral comments must notify the contact person at least 10 days before the meeting date.

ADDRESSES: The meeting will be held in the Natcher Conference Center on the NIH Campus at 9000 Rockville Pike, Bethesda, MD 20894.

FOR FURTHER INFORMATION CONTACT: For further information concerning this meeting, contact Dr. Andrew S. Narva, Executive Secretary of the Kidney Interagency Coordinating Committee, National Institute of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., MSC 5458, Bethesda, MD 20892–5458, telephone: 301–594–8864; FAX: 301–480–3510; email: *healthinfo@niddk.nih.gov.*

SUPPLEMENTARY INFORMATION: The KICC, chaired by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), comprises members of the Department of Health and Human