will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: July 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18969 Filed 7–31–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Surrogate Endpoints for Clinical Trials in Kidney Transplantation; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Surrogate Endpoints for Clinical Trials in Kidney Transplantation.'' The purpose of the public workshop is to discuss potential surrogate endpoints for clinical trials for drugs and therapeutic biologics used in kidney transplantation, with a focus on endpoints in conditions that represent unmet medical needs. This public workshop is intended to provide information and gain perspective from health care providers, academia, and industry on the role of various laboratory, histologic, and other endpoints used to evaluate patient and allograft outcome in clinical trials for kidney transplantation.

Date and Time: The public workshop will be held on September 28, 2015, from 8 a.m. to 6 p.m.

Location: The public workshop will be held at the Residence Inn Marriott, 2850 South Potomac Ave., Arlington, VA 22202. Web site: *http://www.marriott.com/hotels/travel/wasry-residence-inn-arlington-capital-view/.* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register.**) Seating will be available on a first-come, first-served basis.

Contact Person: Ramou Pratt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6193, Silver Spring, MD 20993–0002, 301–796–3928 or 301–796–1600.

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone and fax numbers) to Ramou Pratt (see *Contact Person*) by September 25, 2015. Registration is free for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space-available basis beginning at 8 a.m.

If you need special accommodations because of a disability, please contact Ramou Pratt (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop entitled ''Surrogate Endpoints for Clinical Trials in Kidney Transplantation.'' The purpose of the workshop is to discuss potential clinical or surrogate endpoints and biomarkers for clinical trials for drugs and therapeutic biologics in kidney transplantation. The input from this public workshop will help in developing topics for further discussion and may serve to inform recommendations on potential surrogate endpoints in clinical trials for kidney transplantation. The Agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

This workshop is part of the Agency's program to facilitate the development of surrogate endpoints, clinical endpoints, and other scientific methods for predicting clinical benefit, in accordance with section 901 of the Food and Drug Administration Safety and Innovation Act, titled ''Enhancement of Accelerated Patient Access to New Medical Treatments,'' which was signed into law on July 9, 2012. During the workshop, there will be a discussion on potential surrogate endpoints and their ability to predict clinical benefit.

This public workshop will include discussion of allograft histology and biomarkers, laboratory measures of outcome, and other endpoints that may serve as surrogates for patient morbidity, graft function, and patient and graft survival. Related topics for discussion will include clinically relevant risk factors and prognostic factors in the kidney transplant population. Patient selection and enrichment strategies (inclusion/exclusion criteria) will be considered. The public workshop will include scientific discussion on the following topics:

- Surrogate endpoints and accelerated approval
- Unmet medical need in kidney transplant patients
- Histology: Findings on kidney biopsy (including protocol biopsies)
- Laboratory measurements and outcomes, surrogates and biomarkers
- Patient selection criteria and enrichment strategies
- Risk factors and prognostic factors
- Medication adherence

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information, U.S. Food & Drug Administration, 5630 Fishers Lane, Rm. 1033, Rockville, MD 20857. Transcripts will also be available on the Internet at *http://wcms.fda.gov/FDAgov/Drugs/NewsEvents/ucm449248.htm* approximately 45 days after the workshop.

Dated: July 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18957 Filed 7–31–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2138]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

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 September 2, 2015.