institutions would provide great insight to FDA review staff. The Center encourages applicants to consider including opportunities to discuss patient perspective and meeting the challenges of quality systems design and management as they contribute to the success of the device development life cycle.

CDRH is committed to advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and helping to ensure consumer confidence in medical devices marketed in the United States and throughout the world. The ELP is intended to provide CDRH staff with an opportunity to understand the policies, laboratory and manufacturing practices, and the challenges addressing patient perspective/input, quality system management, and other challenges that impact the device development life cycle. This component is a collaborative effort to enhance communication and facilitate the premarket review process. The Center is committed to understanding current industry practices, innovative technologies, regulatory impacts and needs, and how patient perspective and quality systems management advances the development and evaluation of innovative devices, and to monitoring the performance of marketed devices.

These formal training visits are not intended for FDA to inspect, assess, judge, or perform a regulatory function (*e.g.,* compliance inspection), but rather, they are an opportunity to provide CDRH review staff a better understanding of the products they review, how they are developed, the voice of the patient, challenges related to quality systems development and management in the product life cycle, and how medical devices fit into the larger health care system. CDRH is formally requesting participation from companies, academia, and clinical facilities, medical device incubators and accelerators, health insurers, health technology assessment groups, and others, including those that have previously participated in the ELP or other FDA site visit programs.

CDRH encourages applicants to consider including opportunities to discuss how patient perspective and effective quality systems management contribute to the success of the device development life cycle. Additional information regarding the CDRH ELP, including the table of areas of interest, submission dates and deadlines, a sample request, and an example of the site visit agenda, is available on CDRH's Web site at: *http://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm.* The Center encourages applicants to consider including opportunities to discuss patient perspective and meeting the challenges of Quality Systems Design and Management as they contribute to the success of the device development life cycle.

## II. CDRH ELP

### *A. Areas of Interest*

In this training program, groups of CDRH staff will observe operations in the areas of research, device development, in making coverage decisions and assessments, incorporating patient information and reimbursement, manufacturing, academia, and health care facilities. The areas of interest for visits include various topics identified by managers at CDRH. These areas of interest are listed publicly and are intended to be updated quarterly.

To submit a proposal addressing one of the Center's training needs, visit the link for the table of areas of interest to be addressed at: *http://www.fda.gov/ScienceResearch/ScienceCareerOpportunities/UCM380676.htm*

Once you have determined an area of interest to address in your ELP proposal, follow the instructions in section III to properly fill out the site visit request template and agenda provided at: *http://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM392988.pdf* and at: *http://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM487190.pdf.*

### *B. Site Selection*

CDRH will be responsible for CDRH staff travel expenses associated with the site visits. CDRH will not provide funds to support the training provided by the site to the ELP. Selection of potential facilities will be based on CDRH's priorities for staff training and resources available to fund this program. In addition to logistical and other resource factors, all sites must have a successful compliance record with FDA or another Agency with which FDA has a memorandum of understanding (if applicable). If a site visit involves a visit to a separate physical location of another firm under contract with the site, that firm must agree to participate in the ELP and must also have a satisfactory compliance history, and must be listed in the proposal along with a Facility Establishment Identifier number (FEI #) if applicable.

## III. Request to Participate

Submit proposals for participation with the docket number found in the brackets in the heading of this document. Received requests may be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Additional information regarding the CDRH ELP, including a sample request and an example of a site visit agenda and submission deadlines, is available on CDRH's Web site at: *http://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm.*

Dated: March 17, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–05763 Filed 3–22–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–D–0198]**

### Delayed Graft Function in Kidney Transplantation: Developing Drugs for Prevention; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Delayed Graft Function in Kidney Transplantation: Developing Drugs for Prevention.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the prevention of delayed graft function (DGF) in kidney transplantation.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 21, 2017.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2017–D–0198 for ''Delayed Graft Function in Kidney Transplantation: Developing Drugs for Prevention; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Ozlem Belen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 22, Rm. 6118, Silver Spring, MD 20993–0002, 301–796–0676.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Delayed Graft Function in Kidney Transplantation: Developing Drugs for Prevention.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the prevention of DGF in kidney transplantation.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on developing drugs for the prevention of DGF in kidney transplant. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

## III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: March 20, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–05818 Filed 3–22–17; 8:45 am]

**BILLING CODE 4164–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Center for Scientific Review; 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:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Oncology 1 Basic Translational.

*Date:* April 6, 2017.

*Time:* 1:00 p.m. to 5:00 p.m.