within 1 working day, using the PIN described previously.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log on to the ADUFA Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* and, under Tools and Resources, click ''The Animal Drug User Fee Cover Sheet'' and then click ''Create ADUFA User Fee Cover Sheet.'' For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Drug User Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or supplement. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three—Send the payment for your application as described in section VIII.A.

Step Four—Please submit your application and a copy of the completed Animal Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product, Establishment, and Sponsor Fees

By December 31, 2015, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2016 using this fee schedule. Payment will be due by January 31, 2016. FDA will issue invoices in November 2016 for any products, establishments, and sponsors subject to fees for FY 2016 that qualify for fees after the December 2015 billing.

Dated: July 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18913 Filed 7–31–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Sixth Annual Coalition Against Major Diseases/Food and Drug Administration Scientific Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the sixth annual scientific workshop co-sponsored by the Agency and the Coalition Against Major Diseases (CAMD) Consortium of the Critical Path Institute (C-Path). The purpose of this public workshop is to initiate constructive discussion among scientists from FDA, the CAMD Consortium, and other interested parties regarding ongoing efforts to develop tools and methods to facilitate drug development for Alzheimer's disease and Parkinson's disease.

DATES: The public scientific workshop will be held on October 15, 2015, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for the public scientific 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: Jacqueline Brooks-Leighton, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 21, Rm. 4521, Silver Spring, MD 20993, 240–402–5292, FAX: 301–796–9907, *jacqueline.brooks-leighton@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA and C-Path seek to leverage their combined strengths to create new tools and methods to increase the efficiency of the drug development process and bring new treatments for Alzheimer's disease and Parkinson's disease. This annual public workshop brings together representatives from the pharmaceutical industry, the academic research community, patient advocacy groups, and governmental institutions; including, the National Institute of Aging, the National Institute of Neurological Disorders and Stroke, and the European Medicines Agency.

The objectives of the workshop include:

1. Understanding the accomplishments of CAMD scientific projects
2. Discussing how these tools are currently or will be applied in drug development
3. Obtaining commitment for sharing information/data to begin quantifying benefits of these tools
4. Facilitating robust and open discussion among all parties of drug development in Alzheimer's and Parkinson's diseases

II. Attendance and Registration

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Individuals who wish to participate in the scientific workshop (in person or via the Internet) must register on or before October 1, 2015, by visiting *https://www.SignUp4.net/public/ap.aspx?EID=SIXT10E*.

Early registration is recommended; registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Onsite registration on the day of the scientific workshop will be based on space availability. The registration deadline is October 14, 2015. An agenda will be provided approximately 2 weeks before the scientific workshop at the FDA Meeting Information page, which is available online at: *http://www.fda.gov/Drugs/NewsEvents/ucm410863.htm*.

If you need special accommodations because of a disability, please contact Jacqueline Brooks-Leighton (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the scientific workshop.

A live webcast of this scientific workshop will be viewable at Adobe Connect Link: *https://collaboration.fda.gov/camd101515/* on the day of the scientific workshop. A video record of the scientific workshop will be available at the same Web address for 1 year.

III. 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 (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. 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]

BILLING CODE 4164–01–P

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]

BILLING CODE 4164–01–P

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.