estimates for the implementation and cost study and the impact study components of the current request. The requested extension period is estimated to be two years and three months, from July 1, 2016 to September 30, 2018. Thus, burden hours for all components are annualized over two years and three months.

IMPLEMENTATION AND COST STUDY

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Total annual burden hours [a]
Staff interview topic guide	120	1	1	120	53
Study MIS to track program participation	200	468.75	0.0333	3,125	1,390
Impact Study					
Introductory script:					
Grantee staff	120	9	0.1667	180	80
Program applicants [b]	1,050	1	0.1667	175	78
Baseline survey	1,000	1	0.5833	583	259
Study MIS to conduct random assignment	120	9	0.1667	180	80
Protocol for collecting administrative records	32	1	8	256	114
12 month follow-up survey	1,476	1	0.75	1,107	492

[a] All burden estimates are annualized over 2.25 years.
[b] Five percent of program applicants are not expected to agree to participate in the study; thus there are 5% more program applicants than study participants.

Estimated Total Annual Burden Hours: 2,546.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–09803 Filed 4–26–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–N–2016–1134]

Public Meeting on Patient-Focused Drug Development for Patients Who Have Received an Organ Transplant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for patients who have received an organ transplant. Patient-Focused Drug Development is part of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patient perspectives on the impact of receiving an organ transplant on daily life and patient views on treatment approaches; the input from this public meeting will help in developing topics for further discussion. FDA is also interested in discussing issues related to scientific challenges in developing drugs to manage organ transplantation. In the afternoon, FDA will hold a workshop and provide information for and gain perspective from patients and patient advocacy organizations, health care providers, academic experts, and industry on various aspects of clinical development of drug products intended to manage organ transplantation.

DATES: The public meeting will be held on September 27, 2016, from 9 a.m. to 5 p.m. Please register here for the meeting by September 20, 2016: *http://organtransplantpfdd.eventbrite.com.* Submit electronic or written comments to the public docket by November 27, 2016.

ADDRESSES: The meeting and workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm.1503), Silver Spring, MD 20993–0002. Participants must enter through Building 1 and undergo security screening. For more information on parking and security procedures, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

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–2016–N–1134 for ''Public Meeting on Patient-Focused Drug Development for Patients Who Have Received an Organ Transplant.'' 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.

FDA will post the agenda approximately 5 days before the meeting at: *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm495933.htm.*

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993, 301–796–5003, FAX: 301–847–8443, *graham.thompson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected patients who have received an organ transplant as the focus of a public meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patient perspectives on the severity of a disease and the available therapies for these conditions. Patient-Focused Drug Development is being conducted to fulfill FDA performance commitments that are part of the reauthorization of the PDUFA under Title I of the Food and Drug Safety and Innovation Act (Pub. L. 112–144). The full set of performance commitments is available at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

FDA committed to obtain the patient perspective on 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient communities, and other interested stakeholders.

On July 2, 2015, FDA published a notice (80 FR 32816) in the **Federal Register** announcing the disease areas for meetings in fiscal years 2016–2017, final 2 years of PDUFA V time frame. The Agency used several criteria outlined in that notice to develop the list of disease areas. FDA obtained public comment on the Agency's proposed criteria and potential disease areas through a public docket. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. More information, including the list of disease areas and a general schedule of meetings, is posted at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm.*

II. Public Meeting and Workshop Information

A. Purpose and Scope of the Meeting

The purpose of this Patient-Focused Drug Development meeting is to obtain input on organ transplantation and current approaches to management of organ transplantation. In 2015, over 25,000 people in the United States received an organ transplant. Organ transplantation requires pharmacologic and non-pharmacologic management before and after receipt. There are FDA-approved therapies used to assist the immune system in responding properly to the transplanted organ. Treatment requires a combination of drugs given for the lifetime of a transplanted organ. FDA is committed to working with all stakeholders to develop safe and effective therapies for affected individuals.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief initial patient panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through written comments, which can be submitted to the public docket (see **ADDRESSES**). When submitting comments, if you are commenting on behalf of a child, please indicate that you are doing so and

answer the following questions as much as possible from the patient's perspective.

Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients

1. What have been the most significant changes in your overall health since you received your transplanted organ?

(a) How long has it been since you received your transplant?

2. Focusing on symptoms related to your organ transplant and post-transplant effects, which 1–3 symptoms have the most significant impact on your life? (Examples may include pain, infection, anxiety, etc.)

3. Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your transplant? (Examples of activities may include sleeping through the night, driving, walking/running, exercising, etc.)

(a) How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days? (Examples may include limitations on the ability to undertake physically strenuous activities, restrictions on the ability to travel, lack of appetite, fatigue, etc.)

4. How has your experience with your transplanted organ changed over time? Do particular symptoms come and go as your duration of time with a transplanted organ has increased? If so, do you know of anything that makes your symptoms better? Worse?

5. What worries you most about your health post-transplant?

Topic 2: Patients' Perspectives on Transplant and Treatment Impacts

1. What are you currently doing to maintain your transplanted organ or treat related health concerns following transplantation? (Examples may include immunosuppressants, antibiotics, antivirals, over-the-counter products, and other therapies including non-drug therapies)

(a) How has your post-transplant treatment regimen changed over time, and why?

2. How well does your current treatment regimen manage the most significant symptoms you experience post-transplantation?

(a) How well do these treatments improve your ability to do specific activities that are important to you in your daily life?

(b) How well have these treatments worked for you as your experiences post-transplant have changed over time?

3. What are the most significant downsides to your current treatments, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, need for multiple medications, risk of infection, need for hospitalization, etc.)

(a) What are the biggest challenges you face in maintaining your post-transplant treatment regimen? (Examples of challenges may be bothersome side effects, need for multiple medications, etc.)

4. What specific things would you look for in an ideal treatment for managing your transplanted organ?

In the afternoon, discussion will be related to scientific topics, with the goal of understanding issues that may affect the development of drugs for the treatment of organ transplantation and identifying topics for future discussion. Discussion topics for the afternoon will include the following: Current treatment considerations, adherence, clinical trial designs, and clinical trial endpoints.

B. Meeting Attendance and Participation

If you wish to attend this meeting, visit *http://organtransplantpfdd.eventbrite.com.* Please register by September 20, 2016. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Seating will be limited, so 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. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Graham Thompson (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients also must send to *PatientFocused@fda.hhs.gov* a brief summary of responses to the topic questions by September 12, 2016. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

FDA will hold an open public comment period to give the public an opportunity to comment. Registration for open public comment will occur at the registration desk on the day of the meeting and workshop on a first-come, first-served basis.

Docket Comments: Regardless of if you attend the public meeting, you can submit electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see **ADDRESSES**) by November 27, 2016. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Transcripts: As soon as a transcript is available, FDA will post it at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm495933.htm.*

Dated: April 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09785 Filed 4–26–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0514]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requests for Clinical Laboratory Improvement Amendments Categorization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requests for Clinical Laboratory Improvement Amendments of 1998 (CLIA) categorization of in vitro diagnostic tests when a premarket review is not needed.

DATES: Submit either electronic or written comments on the collection of information by June 27, 2016.