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.

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–2013–N–0514 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Requests for Clinical Laboratory Improvement Amendments Categorization.'' 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.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Requests for Clinical Laboratory Improvement Amendments of 1988 Categorization—42 CFR 493.17—OMB Control Number 0910–0607—Extension

A guidance document entitled ''Guidance for Administrative Procedures for CLIA Categorization'' was released on May 7, 2008. The document describes procedures FDA uses to assign the complexity category to a device. Typically, FDA assigns complexity categorizations to devices at the time of clearance or approval of the device. In this way, no additional burden is incurred by the manufacturer because the labeling (including operating instructions) is included in the premarket notification (510(k)) or premarket approval application (PMA). In some cases, however, a manufacturer may request CLIA categorization even if FDA is not simultaneously reviewing a 510(k) or PMA. One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (*e.g.* name change, exempt from 510(k) review). The guidance recommends that in the correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Request for CLIA Categorization	60	15	900	1	900	$46,800

[1] There are no capital costs associated with this collection of information.

The number of respondents is approximately 60. On average, each respondent will request categorizations (independent of a 510(k) or PMA) 15 times per year. The cost, not including personnel, is estimated at $52 per hour ($52 \times 900$), totaling $46,800. This includes the cost of copying and mailing copies of package inserts and a cover letter, which includes a statement of the reason for the request and reference to the original 510(k) numbers, including regulation numbers and product codes. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (*e.g.,* paper).

Dated: April 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09769 Filed 4–26–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Office of Medical Products and Tobacco; Center for Drug Evaluation and Research; Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Medical Policy has modified its structure. This new organizational structure was approved by the Secretary of Health and Human Services on December 15, 2016, and effective on April 17, 2016.

FOR FURTHER INFORMATION CONTACT: Melanie Keller, Office of Management, Center for Drug Evaluation and Research, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 301–796–3291.

I. Summary

This organization will expand current activities in the Office of Medical Policy and foster efficient oversight of clinical trials conducted through policy initiatives that build quality upfront and science-based inspectional approaches. This will provide an oversight and direction for new and ongoing policy initiatives in broad-based medical and clinical policy areas, including initiatives to improve science and efficiency trials.

The Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Medical Policy has been restructured as follows:

DKKNF. ORGANIZATION. The Office of Medical Policy is headed by the Director, Office of Medical Policy and includes the following organizational units:

Office of Medical Policy
Office of Prescription Drug Promotion
Division of Advertising and Promotion Review I
Division of Advertising and Promotion Review II

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guides (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's Web site at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

Authority: 44 U.S.C. 3101.

Dated: April 19, 2016.

Sylvia M. Burwell,

Secretary of Health and Human Services.

[FR Doc. 2016–09761 Filed 4–26–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than June 27, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the