Drug Administration Staff'' [2] assists FDA staff and regulated industry by describing the user fees associated with 513(g) requests. The Medical Device User Fee Cover Sheet (Form FDA 3601), which accompanies the supplemental material described in this information collection is approved under OMB control number 0910–0511.

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
Center for Devices and Radiological Health 513(g) requests	114	1	114	12	1,368
Center for Biologics Evaluation and Research 513(g) requests	4	1	4	12	48
Total					1,416

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: January 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–00470 Filed 1–12–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0008]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) announces a forthcoming public advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on February 17, 2021, from 9 a.m. Eastern Time to 6 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, *aden.asefa@fda.hhs.gov,* 301–796–0400, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On February 17, 2021, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the Lutonix 014 Drug Coated Balloon Percutaneous Transluminal Angioplasty (PTA) catheter. The proposed Indication for Use for the Lutonix 014 Drug Coated Balloon PTA catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of obstructive *de novo* or non-stented restenotic lesions in native popliteal, tibial, and peroneal arteries up to 320 mm in length and 2.0 to 4.0 mm in diameter.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/circulatory-system-devices-panel.* Select the link for the 2021 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 10, 2021. Oral presentations from the public will be scheduled between approximately 1 p.m. Eastern Time and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time

[2] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-513g-requests-information.*

requested to make their presentation on or before February 2, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 3, 2021.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at *Annmarie.Williams@fda.hhs.gov* or 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–00469 Filed 1–12–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation OMB No. 0906–0034—Extension

Correction

In notice document 2020–28017 appearing on pages 83098–83099 in the issue of Monday, December 21, 2020, make the following correction:

(1) On page 83098, in the second column, in the **DATES** section, change ''January 20, 2021'' to read ''January 21, 2021.''

[FR Doc. C1–2020–28017 Filed 1–12–21; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Privacy Act of 1974; System of Records

AGENCY: National Institutes of Health (NIH), Department of Health and Human Services (HHS).

ACTION: Notice of a Modified System of Records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, the Department of Health and Human Services is updating and renaming an existing system of records maintained by the National Institutes of Health (NIH), 09–25–0165, ''National Institutes of Health (NIH) Office of Loan Repayment and Scholarship (OLRS) Record System, HHS/NIH/OD'' (to be renamed ''NIH Loan Repayment Records''). In a separate Notice of Proposed Rulemaking (NPRM) published elsewhere in today's **Federal Register**, HHS/NIH is proposing to exempt a subset of records in the system of records from certain requirements of the Privacy Act, based on subsection (k)(5) of the Privacy Act.

DATES: The comment period for this modified System of Records Notice (SORN) is co-extensive with the 60-day comment period provided in the companion NPRM also published in today's **Federal Register**. Written comments on the SORN should be submitted on or before March 15, 2021. The modified SORN will be applicable when the proposed exemptions are made effective by publication of a Final Rule, which will not occur until after the 60-day comment period ends and any comments received on the NPRM (or on this SORN) have been addressed.

ADDRESSES: You may submit comments, identified by the Privacy Act System of Records Number (09–25–0165), by any of the following methods: Email: *privacy@mail.nih.gov* and include Privacy Act System of Record (PA SOR) number (09–25–0165) in the subject line of the message. Phone: (301) 402–6201. Fax: (301) 402–0169. Mail or hand-delivery: NIH Privacy Act Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Blvd., Suite 601, MSC 7669, Rockville, MD 20852. Comments received will be available for public inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday, except federal holidays. Please call 301–496–4606 for an appointment.

FOR FURTHER INFORMATION CONTACT: General questions about the proposed modified system of records may be submitted to Celeste Dade-Vinson, NIH Privacy Act Officer, Office of Management Assessment, Office of the Director, National Institutes of Health (NIH), 6011 Executive Blvd., Suite 601, MSC 7669, Rockville, MD 20852, or telephone 301 402–6201.

SUPPLEMENTARY INFORMATION: This system of records (hereafter referred to as the ''NIH Loan Repayment Records''), covers records maintained in a particular NIH information technology (IT) system managed by NIH's Division of Loan Repayment (DLR) that are used to manage and evaluate the intramural and extramural educational Loan Repayment Programs (LRP) at NIH. As of the date of this publication, there are eight such programs that provide student loan repayments for qualified individuals who agree to conduct biomedical and behavioral research; recipients include NIH employee researchers as well as scientists conducting research at non-profit organizations outside NIH. Scholarship program records at NIH are now covered by the following NIH SORNs, so are omitted from modified SORN 09–25–0165:

- 09–25–0014—Clinical Research: Student Records, HHS/NIH/OD/OIR/OE
- 09–25–0108—Personnel: Guest Researchers, Special Volunteers, and Scientists Emeriti, HHS/NIH/OHRM
- 09–25–0140—International Scientific Researchers in Intramural Laboratories, ORS/DIRS
- 09–25–0158—Administration Records of Applicants and Awardees of the Intramural Research Training Awards Program, HHS/NIH/OD/OE

The System of Records Notice (SORN) for System 09–25–0165 has been reformatted in accordance with OMB Circular A–108 and updated with these changes:

- *System name.* The system name has been changed from ''National Institutes of Health (NIH) Office of Loan Repayment and Scholarship Records system, HHS/NIH/OD'' to ''NIH Loan Repayment Records.''
- *Throughout the SORN.* References to scholarship program records have been omitted; for example, the abbreviation ''LRSPs'' is now ''LRPs.''
- *System Location and System Manager.* Office names and addresses have been updated.
- *Authority.* This section has been updated to remove all authorities