proposed collection of 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 for public comment in response to the notice. This notice collects comments on the information collection requirements relating to an existing collection: Developmental Disabilities Protection and Advocacy Statement of Goals and Priorities (0985–0034).

DATES: Submit written comments on the collection of information by November 6, 2015.

ADDRESSES: Submit written comments on the collection of information by fax 202.395.5806 or by email to *OIRA_submission@omb.eop.gov,* Attn: Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Clare Barnett, Administration for Community Living, Administration on Intellectual and Developmental Disabilities, Office of Program Support, One Massachusetts Avenue NW., Room 4204, Washington, DC 20201, 202–357–3426.

SUPPLEMENTARY INFORMATION: Federal statute and regulation require each State Protection and Advocacy (P&A) System annually prepare for public comment a Statement of Goals and Priorities (SGP) for the P&A for Developmental Disabilities (PADD) program for each coming fiscal year. Following the required public input for the coming fiscal year, the P&A is required by Federal statute and regulation to submit the final version of the SGP to the Administration on Intellectual and Developmental Disabilities (AIDD). AIDD reviews the SGP for compliance and will aggregate the information in the SGPs into a national profile of programmatic emphasis for P&A Systems in the coming year to provide an overview of program direction, and permit AIDD to track accomplishments against goals and formulate areas of technical assistance and compliance with Federal requirements. ACL estimates the burden of this collection of information as follows:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
PADD SGP	57	1	44	2,508

Estimated Total Annual Burden Hours: 2,508.

Dated: October 1, 2015.

Kathy Greenlee,

Administrator & Assistant Secretary for Aging.

[FR Doc. 2015–25592 Filed 10–6–15; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Dates and Times: The meeting will be held on November 18, 2015, from 8 a.m. to 6 p.m. and November 19, 2015, from 8 a.m. to 11 a.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900.

Contact Person: Patricio G. Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring, MD 20993–0002, *Patricio.Garcia@fda.hhs.gov*, 301–796–6875, 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 Web site at *http://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 coming to the meeting.

Agenda: On November 18, 2015, the committee will discuss, make recommendations and vote on information regarding the premarket approval application (PMA) for the TransMedics® Organ Care System™ (OCS)—Heart, by TransMedics, Inc. The proposed Indication for Use for the TransMedics® Organ Care System™ (OCS)—Heart, as stated in the PMA, is as follows:

The TransMedics® Organ Care System™ (OCS)—Heart is a portable, ex vivo organ perfusion system intended to preserve a donor heart in a near-normothermic and beating state from retrieval until the eventual transplantation into a suitable recipient.

On November 19, 2015, the committee will discuss and make recommendations regarding the classification of the product code ''LKX'', and the associated device classification name, ''Device, Thermal, Hemorrhoids''. The product code LKX represents a category of devices intended to apply controlled cooling and conductive heating to hemorrhoids. These devices are considered preamendments devices since they were in commercial distribution prior to May 28, 1976, when the Medical Devices Amendments became effective. Some examples of the means by which these devices perform these functions and their respective Indications for Use (IFU)/Intended Use (IU) statements are as follows:

- Uses an aluminum probe that contains a temperature sensitive element to regulate temperature within 2 degrees (between 37 and 46 degrees centigrade).
  - IFU/IU: The apparatus is intended to apply controlled, conductive heating to hemorrhoids.
- Uses a heat applicator inserted into the rectum, applicator contains a battery

operated heater and a sensor which provides temperature control/feedback.

○ IFU/IU: Intended to provide temporary relief of the symptoms of hemorrhoids through the application of mild heating.

• Uses speculum like plastic container containing liquid to cool hemorrhoidal veins

○ IFU/IU: Treatment of external hemorrhoids by applying cold therapy (cryotherapy) directly to swollen hemorrhoidal veins.

The committee will also discuss and make recommendations regarding the classification of the product code ''LRL'', and the associated device classification name, ''Cushion, Hemorrhoid''. The product code LRL represents a category of devices intended to temporarily relieve pain and pressure caused by hemorrhoids. These devices are considered preamendments devices since they were in commercial distribution prior to May 28, 1976, when the Medical Devices Amendments became effective. Some examples of the means by which these devices perform these functions and their respective IFU/IU statements are as follows:

• Uses an injection molded polypropylene copolymer plastic seat attached to a toilet seat (the product is adjustable and is available in round and elongated versions).

○ IFU/IU: For the temporary relief from the pain and pressure of hemorrhoids. The device is for external use only.

• Uses a cushion with an inflatable vinyl exterior and a foam center. An air chamber, when filled, prevents the cushion from compressing the foam. A urethane foam center adds comfort.

○ IFU/IU: Intended for the home convalescent patient with perineal discomfort.

• Uses a cushion that contains two internal molded structures that conform to the patient's shape. Exerts ''slight'' pressure on hemorrhoid. IFU/IU not provided.

The committee will also discuss and make recommendations regarding the classification of the product code ''LKN'', and the associated device classification name, ''Separator, automated, blood cell and plasma, therapeutic''. The product code LKN represents a category of centrifuge-type devices intended to separate blood components and perform therapeutic plasma exchange for the management of serious medical conditions in adults and children. These devices are considered preamendments devices since they were in commercial distribution prior to May 28, 1976, when the Medical Devices Amendments became effective. Some examples of the means by which these devices perform these functions and their respective IFU/IU statements are as follows:

• Utilizes a continuous flow centrifuge (max speed 3000 rpm) to separate source blood from a subject into blood components.

○ IFU/IU: May be used to perform therapeutic plasma exchange.

○ IFU/IU: May be used to perform Red Blood Cell Exchange procedures for the transfusion management of Sickle Cell Disease in adults and children.

• Uses continuous flow access to a rotating centrifuge to separate blood components.

○ IFU/IU: May be used to harvest cellular components from the blood of certain patients where the attending physician feels the removal of such component may benefit the patient.

○ IFU/IU: May be used to remove plasma components and/or fluid selected by the attending physicians.

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 Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

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 November 10, 2015. Oral presentations from the public will be scheduled on November 18, 2015, between approximately 1 p.m. and 2 p.m. and on November 19, 2015, between approximately 8:30 a.m. and 9:30 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit 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 requested to make their presentation on or before November 2, 2015. 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 November 3, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

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 Artair Mallett at *artair.mallett@fda.hhs.gov*, or 301–796–9638, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://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: October 1, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–25466 Filed 10–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0007]

Fee for Using a Rare Pediatric Disease Priority Review Voucher in Fiscal Year 2016; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Fee for Using a Rare Pediatric Disease Priority Review Voucher in Fiscal Year 2016'' that appeared in the **Federal Register** of September 28, 2015 (80 FR 58262). The document announced the fee rate for using a rare pediatric disease priority review voucher for fiscal year 2016. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Food and Drug Administration, Bldg. 32, Rm. 3330, Silver Spring, MD 20993, 301–796–9115, *Lisa.Granger@fda.hhs.gov*.