

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.

SUPPLEMENTARY INFORMATION: In FR Doc. 2015-24508, appearing on page 58262 in the **Federal Register** of Monday, September 28, 2015, the following correction is made:

On page 58262, in the third column, in the headings section of the document, "FDA-2014-N-0007" is corrected to read "FDA-2015-N-0007".

Dated: October 2, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015-25525 Filed 10-6-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health IT Policy Committee Advisory Meeting; Notice of Meeting

AGENCY: Office of the National Coordinator for Health Information Technology, HHS

ACTION: Notice of meeting.

This notice announces updated dates for meetings of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). These meetings will be open to the public.

Name of Committee: Health IT Policy Committee.

General Function of the Committee: To provide recommendations to the National Coordinator on a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information as is consistent with the Federal Health IT Strategic Plan and that includes recommendations on the areas in which standards, implementation specifications, and certification criteria are needed.

2015 Meeting Dates and Times:

- October 6, 2015, from 9:30 a.m. to 3:00 p.m./Eastern Time
- November 10, 2015, from 9:30 a.m. to 3:00 p.m./Eastern Time
- December 8, 2015, from 9:30 a.m. to 3:00 p.m./Eastern Time

For meeting locations, web conference information, and the most up-to-date information, please visit the calendar on the ONC Web site, <http://www.healthit.gov/FACAS/calendar>.

Contact Person: Michelle Consolazio, email: michelle.consolazio@hhs.gov. Please email Michelle Consolazio for the most current information about meetings. 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.

Agenda: The committee will hear reports from its workgroups/task forces and updates from ONC and other federal agencies. ONC intends to make background material available to the public no later than 24 hours prior to the meeting start time. If ONC is unable to post the background material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's Web site after the meeting, at <http://www.healthit.gov/FACAS/health-it-policy-committee>.

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 prior to the meeting date. Oral comments from the public will be scheduled prior to the lunch break and at the conclusion of each meeting. Time allotted for each presentation will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public session, ONC will take written comments after the meeting.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing wireless access or access to electrical outlets.

ONC welcomes the attendance of the public at its advisory committee meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Michelle Consolazio at least seven (7) days in advance of the meeting.

ONC is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.healthit.gov/facas/> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., App. 2).

Dated: September 30, 2015.

Michelle Consolazio,

FACA lead, Office of Policy, Office of the National Coordinator for Health Information Technology.

[FR Doc. 2015-25562 Filed 10-6-15; 8:45 am]

BILLING CODE 4150-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health IT Standards Committee Advisory Meeting; Notice of Meeting

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Notice of meeting.

This notice announces updated dates for meetings of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). These meetings will be open to the public.

Name of Committee: Health IT Standards Committee.

General Function of the Committee: To provide recommendations to the National Coordinator on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption, consistent with the implementation of the Federal Health IT Strategic Plan, and in accordance with policies developed by the Health IT Policy Committee.

2015 Meeting Dates and Times:

- October 6, 2015, from 9:30 a.m. to 3:00 p.m./Eastern Time
- November 3, 2015, from 9:30 a.m. to 3:00 p.m./Eastern Time
- December 10, 2015, from 9:30 a.m. to 12:30 p.m./Eastern Time

For meeting locations, Web conference information, and the most up-to-date information, please visit the calendar on the ONC Web site, <http://www.healthit.gov/FACAS/calendar>

Contact Person: Michelle Consolazio, email: michelle.consolazio@hhs.gov. Please email Michelle Consolazio for the most current information about meetings. 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.

Agenda: The committee will hear reports from its workgroups/task forces and updates from ONC and other federal agencies. ONC intends to make background material available to the public no later than 24 hours prior to the meeting start time. If ONC is unable to post the background material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's Web site after the meeting, at <http://www.healthit.gov/facas/health-it-standards-committee>.

Procedure: Interested persons may present data, information, or views,