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.

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jessica T. Walker, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry.'' The draft guidance document provides establishments that make donor eligibility determinations for donors of HCT/Ps, with recommendations concerning the use of FDA-licensed NAT in donor testing for HBV DNA. FDA considers the use of FDA-licensed HBV NAT in testing HCT/Ps donors to be necessary to adequately and appropriately reduce the risk of transmission of HBV. The FDA-licensed HBV NAT can detect evidence of the viral infection at an earlier stage than the HBsAg and total anti-HBc tests. Therefore, FDA recommends the use of FDA-licensed HBV NAT for testing donors of HCT/Ps for evidence of infection with HBV.

HBV is a major global public health concern and has been transmitted by blood transfusions and tissue transplantation. Available literature has indicated possible transmissions of HBV by hematopoietic stem cells and blood with HBV NAT positive/hepatitis B surface antigen (anti-HBs) positive/HBsAg negative blood, irrespective of anti-HBc test results. In blood donors, adding the HBV NAT testing for HBV reduces the residual risk of transmission of HBV infection beyond that which can be achieved by screening donors using only HBsAg and total anti-HBc tests. In addition, it can detect breakthrough infections in previously vaccinated individuals who are exposed to the virus, and HBV mutants appear to be more likely detected by HBV NAT than by HBsAg assays.

In the United States, there are currently FDA-licensed HBV NAT assays with an indication for screening donor blood samples for Whole Blood and Blood components, other living donors (individual organ donors when specimens are obtained while the donor's heart is still beating), and blood specimens from cadaveric (non-heart-beating) donors. Some of these are multiplex assays that can simultaneously detect HIV, HCV, and HBV in a single blood specimen, thus improving the feasibility of routine NAT testing for HBV. By analogy to the experience in the blood donor setting, it is reasonable to expect that the residual risk of transmission of HBV infection would be reduced by adding HBV NAT to the testing strategy for HCT/P donors. HBV NAT's potential utility in further reducing risk of HBV transmission by transplantation is mainly restricted to the early HBsAg-negative phase of infection. In summary, the available scientific data and the availability of FDA-licensed assays support a recommendation that all HCT/Ps donors should be tested using an FDA-licensed HBV NAT. The draft guidance, when finalized, is intended to supplement previous FDA recommendations to HCT/P establishments concerning donor testing for HBsAg and total anti-HBc, in the 2007 Donor Eligibility Guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the ''Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: January 5, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–00149 Filed 1–7–16; 8:45 am]

BILLING CODE 4164–01–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.

Date and Time: The meeting will be held on February 25, 2016, from 8 a.m. to 6 p.m. and February 26, 2016, from 8 a.m. to 1 p.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. 1611, 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 February 25, 2016, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for ''TOPAS Treatment for Fecal Incontinence,'' by ASTORA Women's Health, LLC. The ''TOPAS Treatment for Fecal Incontinence'' device is a sling device (mesh) to be implanted around the puborectalis muscle (a muscle that contributes towards the maintenance of fecal continence). The proposed Indication for Use (IFU) for the ''TOPAS Treatment for Fecal Incontinence'' device, as stated in the PMA, is as follows:

The ''TOPAS Treatment for Fecal Incontinence'' is intended to treat women with fecal incontinence (also referred to as accidental bowel leakage) who have failed more conservative therapies.

On February 26, 2016, during session I, the committee will discuss and make recommendations regarding the reclassification of urogynecologic surgical mesh instrumentation from class I to class II. The applicable product codes are those related to urogynecologic surgical mesh as follows:

- OTN and the associated device classification name, ''mesh, surgical, synthetic, urogynecologic, for stress urinary incontinence, female, multi-incision;''
- PAG and the associated device classification name, ''mesh, surgical, non-synthetic, urogynecologic, for stress urinary incontinence, female, multi-incision;''
- PAH and the associated device classification name, ''mesh, surgical, synthetic, urogynecologic, for stress urinary incontinence, female, single-incision mini-sling;''
- OTO and the associated device classification name, ''mesh, surgical, synthetic, urogynecologic, for apical vaginal and uterine prolapse, transabdominally placed;''
- PAJ and the associated device classification name, ''mesh, surgical, non-synthetic, urogynecologic, for apical vaginal and uterine prolapse, transabdominally placed;''
- OTP and the associated device classification name, ''mesh, surgical, synthetic, urogynecologic, for pelvic organ prolapse, transvaginally placed'' and
- PAI and the associated device classification name, ''mesh, surgical, non-synthetic, urogynecologic, for pelvic organ prolapse, transvaginally placed.''

Some examples of the means by which these devices perform these functions and their respective IFU/Intended Use (IU) statements are:

- Urogynecologic surgical mesh instrumentation is used:
  - IFU/IU: To aid in insertion, placement, fixation, or anchoring of surgical mesh for procedures including transvaginal pelvic organ prolapse repair, sacrocolpopexy (transabdominal pelvic organ prolapse repair), treatment of female stress urinary incontinence. Examples of such surgical instrumentation include needle passers and trocars, needle guides, fixation tools, and tissue anchors.

The committee, during session II, 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 IFU/IU statements are:

- 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, during session III, will 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:

- 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 required at the time of clearance.

The committee, during session IV, will 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:

- Utilizes a continuous flow centrifuge (max speed 3000 revolutions per minute) 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* and then by scrolling 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 February 17, 2016. Oral presentations from the public will be scheduled on February 25, 2016, between approximately 1 p.m. and 2 p.m. and on February 26, 2016, 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 February 9, 2016. 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 10, 2016.

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 AnnMarie Williams at *annmarie.williams@fda.hhs.gov,* 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 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: January 4, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–00111 Filed 1–7–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4021]

Over-the-Counter Sunscreens: Safety and Effectiveness Data; Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of the comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending the comment period provided in the notice entitled ''Over-the-Counter Sunscreens: Safety and Effectiveness Data; Draft Guidance for Industry; Availability'' that appeared in the **Federal Register** on November 23, 2015 (80 FR 72975). That notice announced the availability of a draft guidance for industry and requested comments to that draft guidance by January 22, 2016. FDA is extending the draft guidance's comment period by 30 days (to February 22, 2016) in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period for the draft guidance by an additional 30 days. Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to permit the Agency to consider your comments before issuing the final version of the guidance, submit either electronic or written comments on the draft guidance by February 22, 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–2015–D–4021 for ''Over-the-Counter Sunscreens: Safety and Effectiveness Data; Draft Guidance for Industry.''