

## ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Total/annual burden hours
Communications for site visit planning .....	6	1	1	6
Discussion guide: Individual and small-group interviews .....	60	1	1.5	90

*Estimated Total Annual Burden Hours: 96.*

**Additional Information:** Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov).

**OMB Comment:** OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Mary Jones,**  
*ACF/OPRE Certifying Officer.*

[FR Doc. 2017-08167 Filed 4-21-17; 8:45 am]

**BILLING CODE 4184-29-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-0001]

#### Gastroenterology and Urology 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) announces a forthcoming public advisory committee meeting of the Gastroenterology and Urology 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 be held on May 17, 2017, from 8 a.m. to 6 p.m.

**ADDRESSES:** Hilton Washington, DC/ North, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

**FOR FURTHER INFORMATION CONTACT:**

Patricio G. Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993-0002, [Patricio.Garcia@fda.hhs.gov](mailto: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.

**SUPPLEMENTARY INFORMATION:**

**Agenda:** On May 17, 2017, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the TRANSMEDICS ORGAN CARE SYSTEM (OCS)—Lung System, by TransMedics, Inc. The proposed Indication for Use, as stated in the PMA, is as follows: The TRANSMEDICS ORGAN CARE SYSTEM (OCS) Lung System is a portable organ perfusion, ventilation, and monitoring medical device intended to preserve donor lungs in a near physiologic, ventilated, and perfused state for transplantation.

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 May 8, 2017. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.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 April 28, 2017. 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 May 1, 2017.

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](mailto: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: April 18, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation and Analysis.*

[FR Doc. 2017-08189 Filed 4-21-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-0001]

#### Safe Use Symposium: A Focus on Reducing Preventable Harm From Drugs in the Outpatient Setting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public symposium.

**SUMMARY:** The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research, Professional Affairs and Stakeholder Engagement Staff (PASES), is hosting a 1-day public symposium entitled "Safe Use Symposium: A Focus on Reducing Preventable Harm From Drugs in the Outpatient Setting." The purpose of this symposium is to discuss sources of preventable harm from drugs in the outpatient setting and to stimulate the exchange of ideas among thought leaders on interventions to reduce preventable harms and how these interventions can be studied.

**DATES:** The public symposium will be held on June 15, 2017, from 8 a.m. to 4 p.m.

**ADDRESSES:** The public symposium will be held at FDA's White Oak campus, 10903 New Hampshire Ave, Bldg. 31 (The Great Room C), Silver Spring, MD 20903. Entrance for the public symposium participants (non-FDA employees) is through Bldg. 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

**FOR FURTHER INFORMATION CONTACT:** Christine Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-4228, email: [CDERSafeUseInitiative@fda.hhs.gov](mailto:CDERSafeUseInitiative@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, Professional Affairs and Stakeholder Engagement Staff (PASES), is hosting a 1-day public symposium entitled "Safe Use Symposium: A Focus on Reducing Preventable Harm From Drugs in the Outpatient Setting." The purpose of this symposium is to discuss sources of preventable harm from drugs in the outpatient setting, such as the use of inappropriate medications in particular age groups, drug-drug interactions, unintended exposures, and misuse; and to stimulate the exchange of ideas among thought leaders on interventions to reduce preventable harms and how these interventions can be studied. This information may assist FDA in identifying significant and unexplored areas of preventable harm from drugs for the purpose of funding future research through the Safe Use Initiative. The symposium will feature presentations on sources of outpatient preventable harms, possible interventions, and future research topics. Areas to be discussed include identifying drugs and populations associated with a higher risk of preventable harm, as well as events which may be amenable to interventions. Methods to measure the effect of interventions and how to apply these to the outpatient setting will also be an important focus of discussion.

Presenters will represent multidisciplinary backgrounds from government, academia, patient safety groups, health care industry, and clinicians. There will be opportunities for interaction between speakers and attendees as well as question and answer sessions.

**Registration:** There is no registration fee to attend the public symposium. Early registration is recommended because seating is limited, and registration will be on a first-come, first-served basis. There will be no onsite registration. Persons interested in attending this symposium must register online at <http://wcms.fda.gov/FDAgov/Drugs/NewsEvents/ucm538670.htm?SSContributor=true>. For those without Internet access, please contact Christine Lee (see **FOR FURTHER INFORMATION CONTACT**) to register. If you need special accommodations due to a disability, please contact Christine Lee at least 7 days in advance.

**Transcripts:** A transcript of the symposium will be available for review at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and on the Internet at <https://www.regulations.gov> approximately 30 days after the

symposium. Transcripts will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <https://www.fda.gov>.

Dated: April 17, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017-08182 Filed 4-21-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-0001]

#### Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). 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 be held on May 17, 2017, from 8:30 a.m. to 4:45 p.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. For those unable to attend in person, the meeting will also be Web Cast and will be available at the following link: <https://collaboration.fda.gov/rsvvaccine0517>. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

**FOR FURTHER INFORMATION CONTACT:** CAPT Serina Hunter-Thomas or Rosanna Harvey, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6307C, Silver Spring, MD 20993-0002, at 240-402-5771 [serina.hunter-thomas@fda.hhs.gov](mailto:serina.hunter-thomas@fda.hhs.gov) and 240-402-8072, [rosanna.harvey@fda.hhs.gov](mailto:rosanna.harvey@fda.hhs.gov), or FDA