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
MedSun facilities participating in the electronic reporting of adverse events program (Form FDA 3670)	250	15	3,750	0.75 (45 minutes)	2,813

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

Dated: April 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08212 Filed 4–11–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Circulatory System 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: Circulatory System 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 May 6 and 7, 2014, from 8 a.m. to 6 p.m.

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

Contact Person: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3063, email: *Jamie.Waterhouse@fda.hhs.gov*, 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 May 6, 2014, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the RESQCPR System sponsored by Advanced Circulatory Systems, Inc. The RESQCPR System is comprised of two devices: the RESQPOD 16.0 Impedance Threshold Device, and the RESQPUMP Active Compression Decompression CPR Device. These devices are used together during manual cardiopulmonary resuscitation (CPR) in an attempt to enhance venous return to the heart and blood flow to vital organs during CPR to ultimately increase survival and neurologic outcome in patients suffering from out of hospital cardiac arrest.

Advanced Circulatory Systems, Inc. has proposed the following indications for use: the RESQCPR System is intended for use in the performance of CPR to increase survival with favorable neurologic function in adult patients with non-traumatic cardiac arrest.

On May 7, 2014, during session I, the committee will discuss and make recommendations regarding the classification of membrane lung for long-term pulmonary support systems, one of the remaining preamendment Class III devices regulated under the 510(k) pathway. A membrane lung for long-term pulmonary support refers to the oxygenator component of an extracorporeal circuit used during long-term procedures, commonly referred to as extracorporeal membrane oxygenation (ECMO). An ECMO procedure provides assisted extracorporeal circulation and physiologic gas exchange of a patient's blood when an acute (reversible) condition prevents the patient's own body from providing the physiologic gas exchange needed to sustain life. The circuit is comprised of multiple device types, including, but not limited to, an oxygenator, blood pump, cannulae, heat exchanger, tubing, filters, monitors/detectors, and other accessories; the circuit components and configuration (e.g., arteriovenous, veno-venous) may differ based on the needs of the individual patient or the condition being treated. ECMO is currently used for patients with acute reversible respiratory or cardiac failure, unresponsive to optimal ventilation and/or pharmacologic management.

On January 8, 2013 the FDA issued a proposed order which, if made final, would make the class III ECMO devices class II subject to premarket notification (510(k)) and special controls. FDA discussed the regulatory history of ECMO devices as part of the proposed order. On September 12, 2013, the classification of ECMO was discussed at a meeting of the Circulatory System Devices Panel. The Panel agreed with FDA's proposal to reclassify ECMO to class II (special controls) as outlined in the January 8, 2013, proposed order, but recommended that a panel be reconvened to discuss use of ECMO in an adult patient population as the September 12, 2013, panel meeting was focused on the use of ECMO in a pediatric patient population.

The discussion at this panel meeting will involve making recommendations regarding regulatory classification to either reconfirm to class III (subject to premarket approval application (PMA)) or reclassify to class II and comment on whether special controls are adequate to assure the safety and effectiveness of this device in an adult patient population.

On May 7, 2014, during session II, the committee will discuss and make recommendations regarding the classification of More-than-Minimally Manipulated Allograft Heart Valves (MMM Allograft HVs). An MMM Allograft HV is a human valve or valved-conduit that has been aseptically recovered from qualified donors, dissected free from the human heart, and then subjected to a manufacturing process(es) which alters the original relevant characteristics of the tissue (cf. 21 CFR 1271.3(f), 21 CFR 1271.10(a)(1), and 21 CFR 1271.20). The valve is then stored until needed by a recipient. An

example of such a manufacturing process is one which intentionally removes the cells and cellular debris, with the goal of reducing in vivo antigenicity.

MMM Allograft HVs are considered preamendment devices because they were found substantially equivalent to devices in commercial distribution prior to May 28, 1976, when the Medical Device Amendments became effective. MMM Allograft HVs are currently regulated under the heading of ''Heart Valve, More than Minimally Manipulated Allograft'', Product Code OHA, as unclassified devices and reviewed under the premarket notification, 510(k), authority. FDA is seeking committee input on the safety and effectiveness of MMM Allograft HVs and the regulatory classification for MMM Allograft HVs.

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 April 28, 2014. On May 6, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. On May 7, oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. for session I and between 2 p.m. and 2:30 p.m. for session II. 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 18, 2014. 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 April 21, 2014.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark, Conference Management Staff, at *James.Clark@fda.hhs.gov* or 301–796–5293 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 4, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–08198 Filed 4–11–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0314]

Ophthalmic 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: Ophthalmic 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 May 13, 2014, from 8 a.m. to 6 p.m.

Location: Holiday Inn Express/Highlands Conference Center, Oak I and II Conference Rooms, 20260 Goldenrod Lane, Germantown, MD 20876. The hotel's phone number is 301–605–1434.

Contact Person: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1552, Silver Spring, MD 20993, 301–796–5290, *Natasha.Facey@fda.hhs.gov*, 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 May 13, 2014, the committee will discuss and make recommendations regarding the guidance documents for contact lenses and contact lens accessories. The guidance for contact lenses entitled ''Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses'' and can be found at: *http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm080928.htm*. The guidance for contact lens accessories entitled ''Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products'' and can be found at: *http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm080218.pdf*. The discussion will include topics such as microbiological and chemical pre-clinical testing, revision of pre-clinical test requirements to address patient non-compliance, modification of rigid gas permeable lens care regimens, and labeling for these devices.

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.