DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Improving Access to Eye Care among Persons at High Risk of Glaucoma, FOA DP14–002, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 9:00 a.m.—6:00 p.m., EST, May 6, 2014 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Improving Access to Eye Care among Persons at High Risk of Glaucoma, FOA DP14–002, initial review.''

Contact Person for More Information: M. Chris Langub, Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway NE., Mailstop F–80, Atlanta, Georgia 30341, Telephone: (770) 488–3585, *EEO6@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Gary J. Johnson,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–08307 Filed 4–11–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1439]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Event Program for Medical Devices (Medical Product Safety Network)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 14, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0471. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Adverse Event Program for Medical Devices (Medical Product Safety Network)—(OMB Control Number 0910–0471)—Extension

Among other things, section 519 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i) authorizes FDA to require (1) manufacturers to report medical device-related deaths, serious injuries, and malfunctions, and (2) user facilities to report device-related deaths directly to manufacturers and FDA and serious injuries to the manufacturer. Section 213 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 519(b) of the FD&C Act relating to mandatory reporting by user facilities of deaths, serious injuries, and serious illnesses associated with the use of medical devices. This amendment legislated the replacement of universal user facility reporting by a system that is limited to a ''. . . subset of user facilities that constitutes a representative profile of user reports'' for device-related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the FD&C Act. This legislation provides FDA with the opportunity to design and implement a national surveillance network, composed of well-trained clinical facilities, to provide high-quality data on medical devices in clinical use. This system is called the Medical Product Safety Network (MedSun).

FDA is seeking OMB clearance to continue to use electronic data collection to obtain the information on Form FDA 3500A (approved under OMB control number 0910–0291) related to medical devices and tissue products from the user facilities participating in MedSun, to obtain a demographic profile of the facilities, and for additional questions which will permit FDA to better understand the cause of reported adverse events. Participation in the program is voluntary and currently includes 250 facilities.

In addition to collecting data on the electronic adverse event report form, MedSun collects additional information from participating sites about reported problems emerging from the MedSun hospitals. This data collection is also voluntary and is collected on the same Web site as the report information.

The burden estimate is based on the number of facilities currently participating in MedSun (250). FDA estimates an average of 15 reports per site annually. This estimate is based on MedSun working to promote reporting in general from the sites, as well as promoting reporting from specific parts of the hospitals, such as the pediatric intensive care units, the electrophysiology laboratories, and the hospital laboratories.

In the **Federal Register** of November 29, 2013 (78 FR 71620), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

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]

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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