## 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]

**BILLING CODE 4163–18–P**

## 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: