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 April 29 and 30, 2013, the Committee will discuss general factors in risk communication about FDA-regulated products, including how to communicate effectively about FDA's adverse event reporting systems, and messaging in the context of competing communicators.

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 12, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on April 29, 2013, and 10:30 a.m. and 11:30 a.m. on April 30, 2013. 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 4, 2013. 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 5, 2013. Interested persons can also log on to *https://collaboration.fda.gov/rcac/* to see and hear the proceedings.

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 Luis G. Bravo 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: March 15, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–06415 Filed 3–20–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–M–1012, FDA–2012–M–1039, FDA–2012–M–1048, FDA–2012–M–1049, FDA–2012–M–1066, FDA–2012–M–1084, FDA–2012–M–1085, FDA–2012–M–1088, FDA–2012–M–1109, FDA–2012–M–1110, FDA–2012–M–1111, FDA–2012–M–1146, FDA–2012–M–1176, FDA–2012–M–1183, and FDA–2012–M–1184]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–6570.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from October 1, 2012, through December 31, 2012. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM OCTOBER 1, 2012, THROUGH DECEMBER 31, 2012

PMA No., Docket No.	Applicant	Trade name	Approval date
P110038, FDA–2012–M–1012	Bolton Medical Inc	Relay® Thoracic Stent-Graft with Plus Delivery System.	September 21, 2012.
P110042, FDA–2012–M–1048	Cameron Health, Inc	Subcutaneous Implantable Defibrillator (S–ICD®) System.	September 28, 2012.
P100003, FDA–2012–M–1039	Globus Medical, Inc	Secure-C Artificial Cervical Disc	September 28, 2012.
P120005, FDA–2012–M–1049	Dexcom, Inc	Dexcom G4 PLATINUM Continuous Glucose Monitoring System.	October 5, 2012.
P120006, FDA–2012–M–1110	TriVascular, Inc	Ovation Abdominal Stent Graft System	October 5, 2012.
P120007, FDA–2012–M–1066	Gen-Probe, Inc	APTIMA® HPV 16 18/45 Genotype Assay.	October 12, 2012.
P110008, FDA–2012–M–1085	Paradigm Spine, LLC	coflex® Interlaminar Technology	October 17, 2012.
P110039, FDA–2012–M–1084	InSightec, Inc	InSightec ExAblate® System	October 18, 2012.
P110021, FDA–2012–M–1088	Edwards Lifesciences, LLC	Edwards SAPIEN™ Transcatheter Heart Valve.	October 19, 2012.
P100040/S008, FDA–2012–M–1109	Medtronic Vascular	Valiant® Thoracic Stent Graft with the Captivia Delivery System.	October 26, 2012.
P100012, FDA–2012–M–1111	NuVasive, Inc	PCM® Cervical Disc System	October 26, 2012.
P120002, FDA–2012–M–1183	Cordis Corporation	S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems..	November 7, 2012
P100022, FDA–2012–M–1146	Cook, Inc	Zilver PTX Drug-Eluting Peripheral Stent.	November 14, 2012.
P100047, FDA–2012–M–1184	HeartWare, Inc	HeartWare® Ventricular Assist System	November 20, 2012.
P120008, FDA–2012–M–1176	Abbott Laboratories	ARCHITECT AFP Assay, ARCHITECT AFP Calibrators and ARCHITECT AFP Controls.	November 28, 2012.

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.*

Dated: March 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–06429 Filed 3–20–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: Ryan White HIV/AIDS Treatment Extension Act of 2009, Part A Minority AIDS Initiative Report (the *Part A MAI Report*): (OMB No. 0915–0304)—EXTENSION

Abstract: HRSA's HIV/AIDS Bureau (HAB) administers the Ryan White HIV/AIDS Part A Program authorized under Title XXVI of the Public Health Service Act (Ryan White HIV/AIDS Treatment Extension Act of 2009). Part A provides emergency relief for areas with substantial need for HIV/AIDS care and support services that are most severely affected by the HIV/AIDS epidemic, including eligible metropolitan areas (EMAs) and Transitional Grant Areas (TGAs). As a component of Part A, the purpose of the Minority AIDS Initiative (MAI) Supplement is to improve access to high quality HIV care, services, and outcomes for individuals in disproportionately impacted communities of color who are living with HIV disease, including African Americans, Latinos, Native Americans, Asian Americans, Native Hawaiians, and Pacific Islanders (Section 2693(b)(2)(A) of the Public Health Service (PHS) Act). Since the purpose of the Part A MAI is to expand access to medical, health, and social support services for disproportionately impacted racial/ethnic minority populations living with HIV/AIDS, it is important that HRSA is able to report on minorities served by the Part A MAI.

The *Part A MAI Report* is a data collection instrument in which grantees report on the number and characteristics of clients served and services provided. The *Part A MAI Report,* first approved for use in March 2006, is designed to collect performance data from Part A grantees. The report has two parts: (1) A web-based data entry application that collects standardized quantitative and qualitative information and (2) an accompanying narrative report. Grantees