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


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.

ADDRESS: 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

<table>
<thead>
<tr>
<th>PMA No., Docket No.</th>
<th>Applicant</th>
<th>Trade name</th>
</tr>
</thead>
<tbody>
<tr>
<td>P110042, FDA–2012–M–1048</td>
<td>Cameron Health Inc</td>
<td>Subcutaneous Implantable Defibrillator (S–ICD®) System.</td>
</tr>
<tr>
<td>P120006, FDA–2012–M–1110</td>
<td>TriVascular, Inc</td>
<td>Ovation Abdominal Stent Graft System</td>
</tr>
<tr>
<td>P110008, FDA–2012–M–1085</td>
<td>Paradigm Spine, LLC</td>
<td>cofflex® Interlaminar Technology</td>
</tr>
<tr>
<td>P110039, FDA–2012–M–1084</td>
<td>InSightec, Inc</td>
<td>InSightec ExAblate® System</td>
</tr>
<tr>
<td>P100040/S008, FDA–2012–M–1109</td>
<td>Medtronic Lifesciences</td>
<td>Valiant® Thoracic Stent Graft with the Captivia Delivery System.</td>
</tr>
<tr>
<td>P100047, FDA–2012–M–1184</td>
<td>HeartWare, Inc</td>
<td>HeartWare® Ventricular Assist System.</td>
</tr>
<tr>
<td>P120008, FDA–2012–M–1176</td>
<td>Abbott Laboratories</td>
<td>ARCHITECT AFP Assay, ARCHITECT AFP Calibrators and ARCHITECT AFP Controls.</td>
</tr>
</tbody>
</table>

Approved date:
- September 21, 2012.
- September 29, 2012.
- October 5, 2012.
- October 5, 2012.
- October 12, 2012.
- October 12, 2012.
- October 17, 2012.
- October 18, 2012.
- October 19, 2012.
- October 26, 2012.
- October 26, 2012.
- November 14, 2012.

II. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.fda.gov/MedicalDevices/Products andMedicalProcedures/Device ApprovalsandClearances/PMA Approvals/default.htm.

Dated: March 15, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

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.


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...