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–303), 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 the Federal Register of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the Federal Register. Instead, the agency now posts this information on the Internet on FDA’s home page at [http://www.fda.gov](http://www.fda.gov). FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the Federal Register, and FDA believes that the Internet is accessible to more people than the Federal Register.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the 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 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 January 1, 2010, through March 31, 2010. 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>
<thead>
<tr>
<th>PMA No.</th>
<th>Docket No.</th>
<th>Applicant</th>
<th>Trade Name</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>P060040/S005</td>
<td>FDA–2010–M–0078</td>
<td>Thoratec Corp.</td>
<td>THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM (LVAS)</td>
<td>January 20, 2010</td>
</tr>
<tr>
<td>H080002</td>
<td>FDA–2010–M–0063</td>
<td>Medtronic, Inc.</td>
<td>MEDTRONIC MELODY TRANSCATHETER PULMONARY VALVE (MODEL PB10) AND MEDTRONIC ENSEMBLE TRANSCATHETER VALVE DELIVERY SYSTEM (NU10)</td>
<td>January 25, 2010</td>
</tr>
<tr>
<td>P090003</td>
<td>FDA–2010–M–0135</td>
<td>Boston Scientific Corp.</td>
<td>EXPRESS LD LIIAC PREMOUNTED STENT SYSTEM</td>
<td>March 5, 2010</td>
</tr>
<tr>
<td>P090006</td>
<td>FDA–2010–M–0158</td>
<td>Medtronic Vascular</td>
<td>COMPLETE SE VASCULAR STENT SYSTEM</td>
<td>March 17, 2010</td>
</tr>
</tbody>
</table>

II. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.fda.gov/cdrh/pmapage.html.

Dated: June 28, 2010.

Nancy Stade,
Acting Associate Director for Regulations and Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–16139 Filed 7–1–10; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel ZAA1 HH01—AA3 Member Conflicts.

Date: July 30, 2010.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Contact Person: Lorraine Gunzerath, PhD, MBA, Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, Office of Extramural Activities, Extramural Project Officer, 5635 Fishers Lane, Room 2121, Bethesda, MD 20892–9304, 301–443–2369.

(Catalogue of Federal Domestic Assistance Program Nos.)


Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–16137 Filed 7–1–10; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1571–N]

Medicare Program; Second Semi-Annual Meeting of the Advisory Panel on Ambulatory Payment Classification Groups—August 23 & 24, 2010

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice announces the second semi-annual meeting of the Advisory Panel on Ambulatory Payment Classification (APC) Groups (the Panel) for 2010. The purpose of the Panel is to review the APC groups and their associated weights and to advise the Secretary of the Department of Health and Human Services (DHHS) (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Administrator) concerning the clinical integrity of the APC groups and their associated weights. We will consider the Panel’s advice as we prepare the final rule that would update the hospital Outpatient Prospective Payment System (OPPS) for CY 2011.

DATES: Meeting Dates: We are scheduling the second semi-annual