

FOR FURTHER INFORMATION CONTACT: Mr. Eskinder Negash, Director, Office of Refugee Resettlement, Administration for Children and Families, 901 D Street, SW., Washington, DC 20047. Telephone: 202-401-5388. E-mail: Eskinder.Negash@acf.hhs.gov.

Dated: May 25, 2011.

Eskinder Negash,
Director, Office of Refugee Resettlement.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2011-M-0034, FDA-2011-M-0040, FDA-2011-M-0041, FDA-2011-M-0039, FDA-2011-M-0035, FDA-2011-M-0056, FDA-2011-M-0105, FDA-2011-M-0131, FDA-2011-M-0132, FDA-2011-M-0170, FDA-2011-M-0175, and FDA-2011-M-0198]

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 the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that amended 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>.

In accordance with section 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 January 1, 2011, through March 31, 2011. 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 JANUARY 1, 2011, THROUGH MARCH 31, 2011

PMA No. Docket No.	Applicant	Trade name	Approval date
P010012 (S230)	Boston Scientific Corp	BOSTON SCIENTIFIC CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS.	September 16, 2010.
FDA-2011-M-0034 P100021	Medtronic Vascular	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM.	December 16, 2010.
FDA-2011-M-0040 P100010	Medtronic Cryocath, LP	ARCTIC FRONT CRYOCATHETER SYSTEM	December 17, 2010.
FDA-2011-M-0041 P070014 (S10)	Bard Peripheral Vascular	LIFESTENT AND LIFESTENT LX VASCULAR STENT SYSTEMS.	December 23, 2010.
FDA-2011-M-0039 P070026	Depuy, Inc	CERAMAX CERAMIC HIP SYSTEM	December 23, 2010.
FDA-2011-M-0035 P100028	Cook Medical, Inc	FORMULA BALLOON-EXPANDABLE RENAL STENT SYSTEM.	January 14, 2011.
FDA-2011-M-0056 P090013	Medtronic, Inc	REVO MRI SURESCAN IPG AND PACING SYSTEM	February 8, 2011.
FDA-2011-M-0105 P080003	Hologic, Inc	SELENIA DIMENSIONS 3D SYSTEMS	February 11, 2011.
FDA-2011-M-0131 P080027 (S1)	OraSure Technologies, Inc ..	ORAQUICK HCV RAPID ANTIBODY TEST	February 18, 2011.
FDA-2011-M-0132 H080005	Elana, Inc	ELANA SURGICAL KIT HUD	March 10, 2011.
FDA-2011-M-0170 P080025	Medtronic Neuromodulation	MEDTRONIC INTERSTIM THERAPY SYSTEM	March 14, 2011.
FDA-2011-M-0175			

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2011, THROUGH MARCH 31, 2011—Continued

PMA No. Docket No.	Applicant	Trade name	Approval date
P80020 FDA-2011-M-0198	Seikagaku Corp	GEL-ONE	March 22, 2011.

II. Electronic Access

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

Dated: May 27, 2011.

Nancy K. Stade,

Deputy Director for Policy Center for Devices and Radiological Health.

[FR Doc. 2011-13692 Filed 6-1-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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 material, 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: Center for Scientific Review Special Emphasis Panel, Member Conflict: Neurodegenerative Cardiovascular Disease and Imaging.

Date: June 16, 2011.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Suzan Nadi, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217B, MSC 7846, Bethesda, MD 20892, 301-435-1259, nadis@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Neurodevelopment and Plasticity.

Date: June 27, 2011.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Laurent Taupenot, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4811, MSC 7850, Bethesda, MD 20892, 301-435-1203, taupenol@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: AIDS/HIV Innovative Research Applications.

Date: July 5, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Allerton Hotel, 701 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Kenneth A Roebuck, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, MSC 7852, Bethesda, MD 20892, (301) 435-1166, roebuckk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Dermatology, Rheumatology and Inflammation.

Date: July 5, 2011.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Aftab A Ansari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4108, MSC 7814, Bethesda, MD 20892, 301-237-9931, ansaria@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Gene Regulation and Genomics.

Date: July 5, 2011.

Time: 10 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Richard A Currie, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1108, MSC 7890, Bethesda, MD 20892, (301) 435-1219, currieri@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel,

Fellowships: Neurodevelopment, Synaptic Plasticity and Neurodegeneration.

Date: July 6-7, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Contact Person: Mary Schueler, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7846, Bethesda, MD 20892, 301-451-0996, marygs@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Emphysema and Lung Development.

Date: July 6-7, 2011.

Time: 9 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: George M Barnas, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4220, MSC 7818, Bethesda, MD 20892, 301-435-0696, barnasg@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Cardiovascular Sciences.

Date: July 7-8, 2011.

Time: 7:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: InterContinental Chicago Hotel, 505 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Lawrence E Boerboom, PhD, Chief, CVRS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7814, Bethesda, MD 20892, (301) 435-8367, boerboom@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Fellowships: Behavioral Neuroscience.

Date: July 7-8, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Contact Person: Kristin Kramer, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5205, MSC 7846, Bethesda, MD 20892, (301) 437-0911, kramerkm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small