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 April 1, 2012, through June 30, 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 APRIL 1, 2012, THROUGH JUNE 30, 2012

PMA No., Docket No.	Applicant	Trade name	Approval date
P020018/S040, FDA–2012–M–0371.	Cook, Inc	Zenith® Fenestrated AAA Endovascular Graft (with the adjunctive Zenith Alignment Stent).	April 4, 2012.
P110029, FDA–2012–M–0372	Abbot Laboratories	ARCHITECT HBsAg Qualitative, ARCHITECT HBsAg Qualitative Confirmatory, ARCHITECT HBsAg Qualitative Confirmatory Manual Diluent, ARCHITECT HBsAg Qualitative Calibrators, and ARCHITECT HBsAg Qualitative Controls.	April 12, 2012.
P110004, FDA–2012–M–0407	Medinol Ltd.	Presillion™ *plus* CoCr Coronary Stent on RX System	April 12, 2012.
P110035, FDA–2012–M–0373	Boston Scientific Corp	Epic™ Vascular Self-Expanding Stent System	April 13, 2012.
P090015, FDA–2012–M–0390	Leica Biosystems	BOND™ ORACLE™ HER2 IHC System	April 18, 2012.
P110010/S001, FDA–2012–M–0562.	Boston Scientific Corp	PROMUS® Element™ Plus Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail™ and Over-the-Wire).	June 1, 2012.
P090026, FDA–2012–M–0638	Beckman Coulter, Inc	Access® Hybritech® p2PSA on the Access Immunoassay Systems.	June 14, 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: September 28, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–24479 Filed 10–3–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: National Heart, Lung, and Blood Institute Special Emphasis Panel; Minority Institutional Training.

Date: October 25, 2012.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Chang Sook Kim, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7179, Bethesda, MD 20892–7924, 301–435–0287, *carolko@mail.nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI Program Project for Triglyceride Metabolism.

Date: October 26, 2012.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Conference Room 9091, Bethesda, MD 20892.

Contact Person: Melissa E Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Rm. 7202, Bethesda, MD 20892, 301–435–0297, *nagelinmh2@nhlbi.nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI SBIR Phase II Contract Review.

Date: October 26, 2012.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

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

Contact Person: YingYing Li-Smerin, Ph.D., MD, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7184, Bethesda, MD 20892–7924, 301–435–0277, *lismerin@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 28, 2012.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–24417 Filed 10–3–12; 8:45 am]

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