

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 July 1, 2009, through September 30, 2009, and from October 1, 2009, through December 31, 2009. There were no denial actions during either 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 JULY 1, 2009, THROUGH DECEMBER 31, 2009.

PMA No. Docket No.	Applicant	Trade Name	Approval Date
P070022 FDA-2009-M-0317	Hologic, Inc.	ADIANA PERMANENT CONTRACEPTION SYSTEM	July 6, 2009
P060008/S11 FDA-2009-M-0369	Boston Scientific Corp.	TAXUS LIBERTE LONG PACLITAXEL ELUING STENT SYSTEM	July 13, 2009
P030050/S2 FDA-2009-M-0370	Sanofi Aventis, LLC	SCULPTRA AESTHETIC	July 28, 2009
P080013 FDA-2009-M-0485	Confluent Surgical, Inc.	DURASEAL XACT SEALANT SYSTEM	September 4, 2009
P080008 FDA-2009-M-0536	bioMerieux, Inc.	VIDAS FREE PSA RT (fPSA) ASSAY	October 8, 2009
P030042 FDA-2009-M-0540	Wright Medical Technology, Inc.	CONSERVE PLUS TOTAL RESURFACING HIP SYSTEM	November 3, 2009

II. Electronic Access

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

Dated: June 17, 2010.

Nancy Stade,

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

[FR Doc. 2010-15259 Filed 6-23-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 contract proposals and

the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel National Childrens Study.

Date: July 12, 2010.

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

Agenda: To review and evaluate contract proposals.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Sathasiva B. Kandasamy, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892-9304, (301) 435-6680, skandasa@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 18, 2010.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-15311 Filed 6-23-10; 8:45 am]

BILLING CODE 4140-01-P

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