

Dated: June 18, 2010.

**Elaine L. Baker,**

*Director, Management Analysis and Services  
Office, Centers for Disease Control and  
Prevention.*

[FR Doc. 2010-15293 Filed 6-23-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Legislative Changes to Primary Care Loan Program Authorized Under Title VII of the Public Health Service Act

**AGENCY:** Health Resources and Services  
Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** On March 23, 2010, President Obama signed into law the Affordable Care Act (ACA), Public Law 111-148. Section 5201 of the ACA changes the Primary Care Loan (PCL) program by: (1) Reducing the number of years for the primary health care service requirement; (2) lowering the interest rate for service default; and (3) eliminating the HHS requirement that parental financial information be submitted for independent students.

**SUPPLEMENTARY INFORMATION:** The PCL program was created through the Health Professions Education Extension Amendments of 1992 (Pub. L. 102-408), which established a new requirement for the use of the Health Professions Student Loan funds for allopathic and osteopathic schools. The PCL program strives to increase the number of primary care physicians by providing long-term, low interest rate loans to full-time students with financial need pursuing a degree in allopathic or osteopathic medicine. Below are details on how the ACA changes Section 723 of the Public Health Service Act (PHSA) regarding administration of the PCL program.

#### Primary Health Care Service Requirement

Under the PCL program, students were required to enter and complete a residency training program in primary health care and practice in primary health care until the PCL borrower's loan was repaid in full. The ACA change requires that for any new PCLs made on or after March 23, 2010, the PCL borrowers are to enter and complete residency training in primary health care and practice in primary health care for either 10 years (including the years spent in residency training) or through the date on which the loan is

repaid in full, whichever occurs first. (Section 5201(a)(1)(B) of the ACA).

#### Service Default Interest Rate

In the past, PCL borrowers who did not fulfill the service requirements and began practicing in a discipline or specialty other than primary health care were penalized by having their interest rate on the PCL recalculated at 18 percent. The ACA change requires that borrowers who receive a PCL on or after March 23, 2010, and fail to comply with the service requirements of the program will have their loans begin to accrue interest at an annual rate of 2 percent greater than the rate the student would pay if compliant. (Section 5201(a)(3) of the ACA.)

#### Parental Financial Information Requirement for Independent Students

Prior to enactment of the new law, independent students were required to provide parental financial information to the school's financial aid office so that the school could consider all financial resources available to the independent student for a PCL. The ACA change eliminates the HHS requirement for independent students to provide parental financial information to determine financial need. At its discretion, a school may still require parental financial information for independent students seeking a PCL. (Section 5201(b) of the ACA.) For this program, an independent student is a student who is at least 24 years of age and has been independent for a minimum of 3 years. Dependent students are still required to submit parental financial information.

The ACA changes to the PCL program will require a participating school to revise its PCL master promissory note for new loans made on or after March 23, 2010, to be consistent with the ACA.

Dated: June 21, 2010.

**Mary K. Wakefield,**

*Administrator.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2009-M-0317, FDA-2009-M-0369, FDA-2009-M-0370, FDA-2009-M-0485, FDA-2009-M-0536, FDA-2009-M-0540]

#### 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, 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>. 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 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]

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## 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](mailto: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.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health and 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 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