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, 2009, through March 31, 2009. 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, 2009, THROUGH MARCH 31, 2009

PMA No. Docket No.	Applicant	Trade Name	Approval Date
P060030 FDA–2009–M–0033	Roche Molecular Systems, Inc.	Cobas ampliprep/cobas taqman HFC test	October 30, 2008
P950009 (S8) FDA–2009–M–0016	BD Diagnostics	BD focal point gs imaging system	December 3, 2008
P080010 FDA–2009–M–0034	Advanced Medical Optics, Inc.	Tecnis multifocal foldable posterior chamber intraocular lens	January 16, 2009
P080021 FDA–2009–M–0049	Advanced Vision Science, Inc.	xact foldable hydrophobic acrylic UV light absorbing posterior chamber IOL	February 2, 2009
P030031 (S11) FDA–2009–M–0071	Biosense Webster, Inc.	Navistar & Celsius thermo cool catheters	February 6, 2009
P070014 FDA–2009–M–0127	Bard Peripheral Vascular, Inc.	lifestent flexstar & flexstar XL vascular stent system	February 13, 2009
P940015 (S12) FDA–2009–M–0128	Genzyme Corp.	Synvisc-One	February 26, 2009
P070005 FDA–2009–M–0135	Synthemed Corp.	Repel-cv bioresorbable adhesion barrier	March 6, 2009
P080002 FDA–2009–M–0159	The Female Health Co.	FC2 female condom	March 10, 2009

II. Electronic Access

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

Dated: September 24, 2009.

Jeffrey Shuren,

Acting Director, Center for Devices and Radiological Health.

[FR Doc. E9–23962 Filed 10–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; 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 applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; Review of P01 applications on Interdisciplinary Research on Oral Manifestations of HIV/AIDS in Vulnerable Populations.

Date: November 12, 2009.

Time: 9 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Victor Henriquez, PhD, Scientific Review Officer, DEA/SRB/NIDCR, 6701 Democracy Blvd., Room 668, Bethesda, MD 20892–4878, 301–451–2405, henriquv@nidcr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: September 29, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–23997 Filed 10–5–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on Tuesday, December 8, 2009, from 8 a.m. to 6 p.m.

Location: Hilton, Washington, DC/Rockville Executive Meeting Center, Plaza Ballroom, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Doreen Kezer, Office of Medical and Scientific Programs (HF-33), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1249, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 8, 2009, the Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, for Abilify (aripiprazole), Argatroban (argatroban), Orencia (abatacept), Humira (adalimumab), Zemuron (rocuronium bromide), Cancidas (caspofungin acetate), Cardiolite (technetium Tc99 sestamibi), Evicel—fibrin sealant (human), Artiss—fibrin sealant (human), Voluven—6% hydroxyethyl starch 130/0.4 in 0.9% sodium chloride injection, Reyataz (atazanavir sulfate), Kaletra (lopinavir/ritonavir), Aptivus (tipranavir), Zetia (ezetimibe), Vytorin (ezetimibe/simvastatin), Ventolin HFA (albuterol sulfate). The committee will also receive a brief update on atypical antipsychotic drugs as requested by the Pediatric Advisory Committee Meeting on November 18, 2008.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before Tuesday, November 24, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before Monday, November 16, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by Tuesday, November 17, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Doreen Kezer at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 1, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–24013 Filed 10–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of The Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Director's Council of Public Representatives.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Director's Council of Public Representatives.

Date: October 30, 2009.

Time: 9 a.m. to 5 p.m.

Agenda: Key topics for this meeting will focus on emerging issues of public importance in biomedical and behavioral research. Further information will be available on the COPR Web site.

Place: National Institutes of Health, Building 31, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20852.

Contact Person: Kelli L. Carrington Executive Secretary/Public Liaison Officer, Office of Communications and Public Liaison, Office of the Director, National Institutes of Health, 9000 Rockville Pike, Building 1, Room 344, Bethesda, MD 20892, 301–594–4575, *carringkmaiI.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: http://www.copr.nih.gov, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from