TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
571.1(c) moderate category	1	1	1	3,000	3,000
571.1(c) complex category	1	1	1	10,000	10,000
571.6 amendment of petition	2	2	4	1,300	5,200
Total Hours					18,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA derived the annual reporting burden estimate for the different categories as follows:

Section 571.1(c)—moderate category: For food additive petition without complex chemistry, manufacturing, efficacy, or safety issues, the estimated time requirement per petition is approximately 3,000 hours. An average of 1 (one) petitions of this type is received on an annual basis, resulting in a burden of 3,000 hours.

Section 571.1(c)—complex category: For a food additive petition with complex chemistry, manufacturing, efficacy, and/or safety issues, the estimated time requirement per petition is approximately 10,000 hours. An average of 1 (one) petition of this type is received on an annual basis, resulting in a burden of 10,000 hours.

Section 571.6: For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. An average of 4 (four) petitions of this type is received on an annual basis, resulting in a burden of 5,200 hours.

Thus, the estimated total annual burden for this information collection is 18,200 hours.

Dated: September 29, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–24047 Filed 10–05–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), announces the establishment of the Interagency Breast Cancer and Environmental Research Coordinating Committee (Committee).

The Committee shall coordinate all efforts within the Department of Health and Human Services to share and coordinate information on existing research activities, and make recommendations to the Secretary DHHS, the National Institutes of Health and other Federal agencies regarding how to improve existing research programs.

The Committee's primary mission is to facilitate the efficient and effective exchange of information on breast cancer research activities among the member agencies, and to coordinate solicitation of proposals for collaborative, multidisciplinary research, including proposals to evaluate environmental and genomic factors that may be related to the etiology of breast cancer.

Duration of this committee is two years from the date the Charter is filed.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. E9–23974 Filed 10–5–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2009–M–0033, FDA–2009–M–0016, FDA–2009–M–0034, FDA–2009–M–0049, FDA–2009–M–0071, FDA–2009–M–0127, FDA–2009–M–0128, FDA–2009–M–0135, FDA–2009–M–0159]

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 (HFZ–402), 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 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.