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, 2015, through June 30, 2015. 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, 2015 THROUGH JUNE 30, 2015

PMA No., Docket No.	Applicant	Trade name	Approval date
P140003, FDA–2015–M–1177	ABIOMED, Inc	Impella® 2.5 System	3/23/2015
P130014, FDA–2015–M–1065	HyperBranch Medical Technology, Inc.	Adherus® AutoSpray Dural Sealant	3/30/2015
P130021/S010, FDA–2015–M–1064.	Medtronic CoreValve, LLC	Medtronic CoreValve® System	3/30/2015
P110015, FDA–2015–M–1178	Advanced Breath Diagnostics, LLC.	Gastric Emptying Breath Test (GEBT)	4/6/2015
P040020/S050, FDA–2015–M–1325.	Alcon Research, Ltd	AcrySof IQ ReSTOR +2.5 D Multifocal Intraocular Lens	4/13/2015
P120023, FDA–2015–M–1326	AcuFocus™, Inc	KAMRA™ inlay	4/17/2015
H130007, FDA–2014–M–2247	CVRx®, Inc	Barostim neo™ Legacy System	12/12/2014
P140011, FDA–2015–M–1460	Siemens Medical Solutions USA, Inc.	MAMMOMAT Inspiration with Tomosynthesis Option	4/21/2015
P120017, FDA–2015–M–1461	Medtronic, Inc	Model 5071 Lead	4/27/2015
P130012, FDA–2015–M–1557	Greatbatch Medical	Myopore Sutureless Myocardial Pacing Lead	4/30/2015
P140023, FDA–2015–M–1708	Roche Molecular Systems, Inc	cobas® KRAS Mutation Test	5/7/2015
P130022, FDA–2015–M–1709	Nevro Corp	Nevro Senza Spinal Cord Stimulation (SCS) System	5/8/2015
P140026, FDA–2015–M–1956	Silk Road Medical, Inc	ENROUTE™ Transcarotid Stent System	5/18/2015
P140004, FDA–2015–M–1957	Vertiflex®, Inc	Superion® InterSpinous Spacer	5/20/2015
P140002, FDA–2015–M–1958	Terumo Medical Corp	Misago® Peripheral Self-expanding Stent System	5/22/2015
P120005/S031, FDA–2015–M–1959.	Dexcom, Inc	Dexcom G4®PLATINUM (Pediatric) Continuous Glucose Monitoring System.	5/22/2015
P110010/S096, FDA–2015–M–2077.	Boston Scientific Corp	PROMUS® Element™ Plus and Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail™ and Over-the-Wire).	6/1/2015
P050052/S049, FDA–2015–M–2078.	Merz North America	Radiesse® Injectable Implant	6/4/2015

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 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–25352 Filed 10–5–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0748]

Agency Information Collection Activities; Proposed Collection; Submission for Office of Management and Budget Review; Guidance for Industry on Generic Drug User Fee Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 5, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0727. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Drug User Fee Cover Sheet; Form FDA 3794 OMB Control Number 0910–0727—Extension

On July 9, 2012, the Generic Drug User Fee Act (GDUFA) (Pub. L. 112–144, Title III) was signed into law by the President. GDUFA, designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry, requires that generic drug manufacturers pay user fees to finance critical and measurable program enhancements. The user fees required by GDUFA are as follows: (1) A one-time fee for original abbreviated new drug applications (ANDAs) pending on October 1, 2012 (also known as backlog applications); (2) fees for type II active pharmaceutical ingredient (API) and final dosage form (FDF) facilities; (3) fees for new ANDAs and prior approval supplements (PASs); and (4) a one-time fee for drug master files (DMFs).

The purpose of this notice is to solicit feedback on the collection of information in an electronic form used to calculate and pay generic drug user fees. Proposed Form FDA 3794, the Generic Drug User Fee Cover Sheet, requests the minimum necessary information to determine if a person has satisfied all relevant user fee obligations. The proposed form is modeled on other FDA user fee cover sheets, including Form FDA 3397, the Prescription Drug User Fee Act Cover Sheet. The information collected would be used by FDA to initiate the administrative screening of generic drug submissions and DMFs, support the inspection of generic drug facilities, and otherwise support the generic drug program. A copy of the proposed form will be available in the docket for this notice.

Respondents to this proposed collection of information would be potential or actual generic application holders and/or related manufacturers (manufacturers of FDF and/or APIs). Companies with multiple applications will submit a cover sheet for each application and facility. Based on FDA's database of application holders and related manufacturers, we estimate that approximately 460 companies would submit a total of 3,544 cover sheets annually to pay for application and facility user fees. FDA estimates that the 3,544 annual cover sheet responses would break down as follows: 1,439 facilities fees, 942 ANDAs, 502 PASs, and 661 Type II API DMFs. The estimated hours per response are based on FDA's past experience with other submissions and range from approximately 0.1 to 0.5 hours. The hours per response are estimated at the upper end of the range to be conservative.

In the **Federal Register** of June 2, 2015 (80 FR 31388), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3794	460	7.7	3,544	0.5 (30 minutes)	1,772

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

Dated: September 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–25360 Filed 10–5–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; 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: Arthritis and Musculoskeletal and Skin Diseases Initial Review Group; Arthritis and Musculoskeletal and Skin Diseases Clinical Trials Review Committee: AMSC–1 Clinical Trials Review Meeting.

Date: October 27–28, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Charles H. Washabaugh, Ph.D., Scientific Review Officer, Scientific Review Branch, NIAMS/NIH, 6701 Democracy Boulevard, Suite 816, Bethesda, MD 20892, 301–594–4952, *washabac@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: September 30, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–25317 Filed 10–5–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 Institute of Neurological Disorders and Stroke Special Emphasis Panel; NINDS Research Resource Opportunities Review.

Date: November 2, 2015.

Time: 11:00 a.m. to 12:30 p.m.