ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Performance measure reporting form (for private sector affected public)	103	2	0.8	165
Performance measure reporting form (for State, local, and tribal government affected public)	15	2	0.8	24
Estimated Total Annual Burden Hours				189

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–7285, *Email: OIRA_SUBMISSION@OMB.EOP.GOV*, *Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–13602 Filed 6–5–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0536]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Cover Sheet, Form FDA 3601

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Form FDA 3601, entitled ''Medical Device User Fee Cover Sheet,'' which must be submitted along with certain medical device product applications, supplements, and fee payment of those applications.

DATES: Submit either electronic or written comments on the collection of information by August 6, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device User Fee Cover Sheet—Form FDA 3601 (OMB Control Number 0910–0511)—Extension

The Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), and the Medical Device User Fee Amendments of 2007 (Title II of the Food and Drug Administration Amendments Act of 2007), authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the Agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the ''Medical Device User Fee Cover Sheet,'' is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees.

The form provides a cross-reference between the fees submitted for an application with the actual submitted application by using a unique number

tracking system. The information collected is used by FDA's Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new medical device applications and supplemental applications.

The total number of annual responses is based on the number of cover sheet submissions received by FDA in fiscal years 2009 through 2011. FDA received cover sheets for the following medical device submissions (average annual): 38 premarket approval applications (PMA, PDP, PMR, BLA),[1] 3,561 premarket notifications, 12 panel track supplements, 180 real-time supplements, 127 180-day supplements, 749 30-day notices, 84 513(g) requests, and 463 annual fees for periodic reporting. The number of received annual responses included the cover sheets for applications that were qualified for small businesses and fee waivers or reductions. The estimated hours per response are based on past FDA experience with the various cover sheet submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates (18 minutes).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Form Number	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3601	5,214	1	5,214	.30	1,564

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

Dated: May 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–13666 Filed 6–5–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Reimbursement Rates for Calendar Year 2012

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: Notice is given that the Director of Indian Health Service (IHS), under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*), has approved the following rates for inpatient and outpatient medical care provided by IHS facilities for Calendar Year 2012 for Medicare and Medicaid beneficiaries and beneficiaries of other Federal programs. The Medicare Part A inpatient rates are excluded from the table below as they are paid based on the prospective payment system. Since the inpatient rates set forth below do not include all physician services and practitioner services, additional payment may be available to the extent that those services meet applicable requirements.

Inpatient Hospital Per Diem Rate (Excludes Physician/Practitioner Services)

Calendar Year 2012

Lower 48 States: $2,169

Alaska: $2,350

Outpatient per Visit Rate (Excluding Medicare)

Calendar Year 2012

Lower 48 States: $317

Alaska: $515

Outpatient per Visit Rate (Medicare)

Calendar Year 2012

Lower 48 States: $273

Alaska: $468

Medicare Part B Inpatient Ancillary Per Diem Rate

Calendar Year 2012

Lower 48 States: $477

Alaska: $811

Outpatient Surgery Rate (Medicare)

Established Medicare rates for freestanding Ambulatory Surgery Centers.

Effective Date for Calendar Year 2012 Rates

Consistent with previous annual rate revisions, the Calendar Year 2012 rates will be effective for services provided on/or after January 1, 2012 to the extent consistent with payment authorities including the applicable Medicaid State plan.

Dated: February 9, 2012.

Yvette Roubideaux,

Director, Indian Health Service.

[FR Doc. 2012–13627 Filed 6–5–12; 8:45 am]

BILLING CODE 4165–16–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 materials, 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 Initial Review Group; Neurological Sciences and Disorders K.

Date: June 25–26, 2012.

Time: 8:00 a.m. to 9:00 a.m.

Agenda: To review and evaluate grant applications.

Place: InterContinental Chicago Hotel, 505 North Michigan Avenue, Chicago, IL 60611.

[1] PMA means premarket approval application, PDP means product development protocol, PMR means postmarketing requirements, and BLA means biologics license applications.