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.

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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]

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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.