

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.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Elizabeth A Webber, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-1917, webbere@mail.nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; T32 Meeting.

Date: November 9-10, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3204, MSC 9529, Bethesda, MD 20892-9529, 301-496-0660, benzingw@mail.nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Clinical Trials SEP.

Date: November 12-13, 2015.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-435-6033, rajarams@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: September 30, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee 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 Special Grants Review Committee.

Date: October 29-30, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington DC/Rockville Hotel Hilton Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Helen Lin, Ph.D., Scientific Review Officer, NIH/NIAMS/RB, 6701 Democracy Blvd., Suite 800, Plaza One, Bethesda, MD 20817, 301-594-4952, linh1@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. 2015-25316 Filed 10-5-15; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651-0057]

Agency Information Collection Activities: Country of Origin Marking Requirements for Containers or Holders

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Country of Origin Marking Requirements for Containers or Holders. CBP is proposing that this information collection be extended with

no change to the burden hours or to the information required. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before December 7, 2015 to be assured of consideration.

ADDRESSES: Written comments may be mailed to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229-1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229-1177, at 202-325-0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: Country of Origin Marking Requirements for Containers or Holders.

OMB Number: 1651-0057.

Abstract: Section 304 of the Tariff Act of 1930, as amended, 19 U.S.C. 1304, requires each imported article of foreign origin, or its container, to be marked in a conspicuous place as legibly, indelibly and permanently as the nature of the article or container permits, with the English name of the country of origin. The marking informs the ultimate purchaser in the United States of the name country in which the article was manufactured or produced. The marking