20852, 301–796–5733, *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 Program

OMB Control Number 0910–0727—Revision

This information collection supports implementation of FDA's Generic Drug User Fee program. The Generic Drug User Fee Amendments (GDUFA) (Pub. L. 112–144, Title 111) were enacted to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA authorizes FDA to assess user fees to fund critical and measurable enhancements to the performance of FDA's generic drugs program, bringing greater predictability and timeliness to the review of generic drug applications. GDUFA is currently authorized through September 30, 2022, with reauthorization activities currently underway. For more information regarding GDUFA and ongoing implementation, we invite you to visit our website at *https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments.*

GDUFA is based on an agreement negotiated by FDA and representatives of the generic drug industry intended to address continuing regulatory challenges. GDUFA reflects input received during an open process that includes regular public meetings, posting of meeting minutes, and consideration of comments from a public docket. We are revising the information collection to include the current GDUFA agreement, or ''goals letter,'' as reflected in the document ''GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022,'' available for download from our website at *https://www.fda.gov/media/101052/download.* The performance goals and program enhancements specified in the goals letter apply to aspects of the generic drug review program that are important for facilitating timely access to quality, affordable generic medicines. FDA is committed to meeting the performance goals specified in the goals letter and to continuous improvement of its performance.

Included among the performance goals is the issuance of topic-specific guidance documents. We maintain a searchable guidance database on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* In publishing the respective notices of availability for each guidance document, we include an analysis under the PRA and invite public comment on the associated information collection recommendations. In addition, all Agency guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time.

We have developed Form FDA 3794, the Generic Drug User Fee Cover Sheet, available at *https://www.fda.gov/industry/fda-user-fee-programs* which requests the minimum necessary information from generic drug applicants to account for and track user fees and to determine the amount of the fee required. Applicants complete and submit the cover sheets to accompany payments. While applicants may submit payment through multiple means, all cover sheets are prepared using FDA's web-based electronic User Fee System. Upon submitting the completed cover sheet, the User Fee System generates a user fee identification number, which is provided to applicants at the bottom of the cover sheet. It also notes the correct fiscal year user fee assessment that is due for the submission or program. FDA requests that applicants submit a copy of this completed cover sheet along with the abbreviated new drug application, as well as other additional GDUFA fees, so FDA can verify that the applicant has paid the correct user fee and their account is current.

Respondents to the information collection are potential or actual generic drug application holders or related active pharmaceutical ingredient and finished dosage form manufacturers. Companies with multiple user fee obligations may submit a cover sheet for each user fee obligation.

In the **Federal Register** of November 19, 2021 (86 FR 64945), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form FDA 3794	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Generic Drug User Fee Cover Sheet	500	7.616	3,808	0.5(30 minutes)	1,904

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

Based on a review of the information collection, we have retained the currently approved burden estimate.

Dated: February 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02689 Filed 2–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Allergy and Infectious Diseases Special Emphasis Panel NIAID New Innovators Awards (DP2 Clinical Trial Not Allowed).

Date: March 10–11, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41B, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Brenda Lange-Gustafson, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41B, Rockville, MD 20852, (240) 669–5047, *bgustafson@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: February 3, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–02660 Filed 2–8–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Allergy and Infectious Diseases, Special Emphasis Panel; NIAID, Clinical Trial Implementation Cooperative Agreement (U01 Clinical Trial Required) and NIAID Clinical Trial Planning Grants (R34 Clinical Trial Not Allowed).

Date: March 4, 2022.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G58, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Anuja Mathew, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G58, Rockville, MD 20852, 301–761–6911, *anuja.mathew@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS).

Dated: February 3, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–02661 Filed 2–8–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0050]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0005

AGENCY: Coast Guard, DHS.

ACTION: Sixty-Day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0005, Application and Permit to Handle Hazardous Materials; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before April 11, 2022.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2022–0050] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–6P), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE. SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2022–0050], and must be received by April 11, 2022.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email