

collection is 0910–0834. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, PRASStaff@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.

Postmarketing Information Sharing Among Constituent Part Applicants for Combination Products—21 CFR 4.103

OMB Control Number 0910–0834—Extension

This information collection request applies to “constituent part applicants” as defined under 21 CFR 4.101 (*i.e.*, any person holding an application under which a constituent part (drug, device, or biological product) of a combination product received marketing authorization if the other constituent

part(s) received marketing authorization under an application held by a different person). Under this collection, constituent part applicants must share safety information they receive related to certain events with the other constituent part applicant(s) and maintain associated records.¹

In the **Federal Register** of April 30, 2020 (85 FR 23971), we 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 THIRD-PARTY DISCLOSURE AND RECORDKEEPING BURDEN

21 CFR section; activity	Number of respondents/recordkeepers	Number of disclosures/records per respondent/recordkeeper	Total annual disclosures/records	Average burden per disclosure/recordkeeping	Total hours
4.103, Sharing information with other constituent part applicants.	33	18	594	0.35 (21 minutes)	208
4.103(b) and 4.105(a)(2), Records of information shared by constituent part applicants.	33	18	594	0.1 (6 minutes)	59
Total	267

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. We note in this regard that FDA extended the compliance date for 21 CFR part 4, subpart B, until July 2020 for most combination products, and until January 2021 for the remainder, in response to stakeholder feedback, to ensure that Combination Product Applicants have sufficient time to update reporting and recordkeeping systems and procedures.² Consequently, entities subject to this rule have not yet had to comply with this information request.

Dated: July 30, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17041 Filed 8–4–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Notice is hereby given of a meeting of the HEAL (Helping to End Addiction Long-term) Multi-Disciplinary Working Group.

The meeting will be open to the public as indicated below via NIH Videocast. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended. The program documents and the discussions could disclose confidential trade secrets or commercial property

such as patentable material, and personal information concerning individuals associated with the program documents, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: HEAL Multi-Disciplinary Working Group Meeting.

Date: August 31, 2020.

Open: August 31, 2020, 9:00 a.m. to 1:00 p.m.

Closed: August 31, 2020, 1:00 p.m. to 2:50 p.m.

Open: August 31, 2020, 2:50 p.m. to 4:30 p.m.

Agenda: Provide an update on Helping to End Addiction Long-Term (HEAL) Initiative projects and obtain expertise from MDWG relevant to the NIH HEAL Initiative and to specific HEAL projects.

Videocast: The open portion of the meeting will be live webcast at: <https://videocast.nih.gov/>.

Place: National Institutes of Health Building 1, Wilson Hall, 1 Center Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rebecca G. Baker, Ph.D., Office of the Director, National Institutes of

¹ The Postmarketing Safety Reporting (PMSR) information collections for drugs, biological products, and devices found in §§ 314.80, 314.81, 600.80, 600.81, 606.170, 606.171, 803.50, 803.53, 803.56, 806.10, and 806.20 (21 CFR 314.80, 314.81, 600.80, 600.81, 606.170, 606.171, 803.50, 803.53, 803.56, 806.10, and 806.20) have already been approved and are in effect or their extension is being sought separately as required, including with respect to burden for combination products (reflected in the authorization for OMB control

number 0910–0834, but, therefore, not addressed in this extension request). The pertinent PMSR information collection provisions for § 314.80(c) and (e), as well as for § 314.81(b) are approved under OMB control numbers 0910–0001, 0910–0230, and 0910–0291. The information collection provisions for §§ 600.80 and 600.81 are approved under OMB control number 0910–0308. Those for § 606.170 are approved under OMB control number 0910–0116. Those for § 606.171 are approved under OMB control number 0910–0458. The information

collection provisions for §§ 803.50, 803.53, and 803.56 are approved under OMB control numbers 0910–0291 and 0910–0437. The information collection provisions for §§ 806.10 and 806.20 are approved under OMB control number 0910–0359.

² See Compliance Policy for Combination Product Postmarketing Safety Reporting (April 2019) (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-policy-combination-product-postmarketing-safety-reporting>).

Health, 1 Center Drive, Room 103A,
Bethesda, MD 20892, (301) 402-1994,
Rebecca.baker@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Office of the Director for the NIH HEAL Initiative home page: <https://heal.nih.gov/news> where an agenda and any additional information for the meeting will be posted when available.

(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: July 30, 2020.

Tyeshia M. Roberson,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-17022 Filed 8-4-20; 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; Emergency Awards: Rapid Investigation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and Coronavirus Disease 2019 (COVID-19).

Date: September 1, 2020.

Time: 11:00 a.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 3G30, Rockville, MD 20892 (Virtual Meeting).

Contact Person: John C. Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 1206, Bethesda, MD 20892, (301) 435-2398, pughjohn@csr.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: July 30, 2020.

Tyeshia M. Roberson,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-17020 Filed 8-4-20; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Literature Selection Technical Review Committee.

The meeting will be open to the public as indicated below. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The portions of the meeting devoted to the review and evaluation of journals for potential indexing by the National Library of Medicine will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended. Premature disclosure of the titles of the journals as potential titles to be indexed by the National Library of Medicine, the discussions, and the presence of individuals associated with these publications could significantly frustrate the review and evaluation of individual journals.

Name of Committee: Literature Selection Technical Review Committee.

Date: October 22-23, 2020.

Open: October 22, 2020, 8:30 a.m. to 10:45 a.m.

Agenda: Program Discussion.

Place: Virtual Meeting.

Closed: October 22, 2020, 10:45 a.m. to 5:00 p.m.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Closed: October 23, 2020, 8:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Contact Person: Dianne Babski, Acting Associate Director, Division of Library

Operations, National Library of Medicine, 8600 Rockville Pike, Building 38, Room 2W04A, Bethesda, MD 20894, 301-827-4729, babskid@mail.nih.gov.

Any member of the public may submit written comments no later than 15 days after the meeting. Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS).

Dated: July 31, 2020.

Ronald J. Livingston, Jr.,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-17096 Filed 8-4-20; 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, 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; Fellowship review.

Date: September 16, 2020.

Time: 10:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NSC Building, 6001 Executive Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Deanna Lynn Adkins, Ph.D., Scientific Review Officer, Scientific Review Branch, NSC Building, Bethesda, MD 20892, 301-496-9223, deanna.adkins@nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Translational Neural, Brain and Pain Relief Devices.

Date: October 13-14, 2020.