

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN—BIOLOGICAL PRODUCTS ¹

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours
600.12; ² Maintenance of Records	131	40.145	5,259	32	168,288
600.12(b)(2); Recall Records	216	3,4028	735	24	17,640
600.80(c)(1) and 600.80(k); AER Records	109	7,503.95	817,931	1	817,931
Total					1,003,859

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

² The recordkeeping requirements in § 610.18(b) are included in the estimate for § 600.12.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN—COMBINATION PRODUCTS ¹

21 CFR section; activity	Number of respondents	Number of disclosures per respondents	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
4.102, 4.103, 4.104, 4.105; Postmarketing Safety Reporting for Combination Products, including associated reports and sharing information with other constituent part applicants.	11	18	198	0.35 (21 minutes) ...	69

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

The burden for this information collection has changed since the last OMB approval. The reporting and recordkeeping burden has increased mostly due to an increase in the number of AER reports submitted to FDA and the associated recordkeeping with these reports. We have also added burden we believe attributable to post marketing safety reporting and attendant recordkeeping and disclosures, as required under part 4, subpart B.

Dated: September 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–21252 Filed 9–27–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 1009 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 General Medical Sciences Special Emphasis Panel; Renewal of Centers of Biomedical Research Excellence (COBRE) (Phase 2).

Date: November 7–8, 2023.

Time: 9:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 (Virtual Meeting).

Contact Person: Nina Sidorova, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, MSC 6200, Room 3AN18–01, Bethesda, Maryland 20892, 301–594–3663, sidorova@nigms.nih.gov.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Review of MOSAIC K99/R00 applications.

Date: November 9, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 (Virtual Meeting).

Contact Person: Rebecca H. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, MSC 6200, Room 3AN12B, Bethesda, Maryland 20892, 301–594–2771, johnsonrh@nigms.nih.gov.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Review of Support for Research Excellence (SuRE) Program (R16).

Date: November 17, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 (Virtual Meeting).

Contact Person: Rebecca H. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, MSC 6200, Room 3AN12B, Bethesda, Maryland 20892, 301–594–2771, johnsonrh@nigms.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 22, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 1009 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: Heart, Lung, and Blood Initial Review Group; NHLBI