TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity and 21 CFR part/section	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
510(k) summary (807.92)		2,725	1	2,725	4	10,900
510(k) statement (807.93)		215	1	215	10	2,150
510(k) submission (807 subpart E)—using eSTAR format.	4062, 4078	100	1	100	40	4,000
Guidance Document Recommendations						
Submitting information associated with requests for recognition of a voluntary consensus standard.		9	1	9	1	9
Annual reporting for custom devices under 520(b) of the FD&C Act.		34	1	34	40	1,360
"Form FDA 3674—Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions"						
Certification to accompany 510(k) submissions.	3674	3,800	1	3,800	0.75 (45 minutes)	2,850
Electronic Submission Template and Resource (eSTAR)						
eSTAR setup—one-time burden		80	1	80	0.08 (5 minutes)	6
Total				12,670		323,379

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

Both the regulations in part 807, subpart E and the associated guidance documents prescribe specific format and content elements necessary for FDA action on submissions. Based on recent trends, an estimated 3,800 submissions are expected each year. Our administrative and technical staff, who are familiar with the requirements for submission of premarket notifications, estimate that it takes an average of 79.25 hours to prepare a submission. Because the PRA defines a recordkeeping requirement to include a requirement to report those records to the Federal government, we account for burden associated with preparing, transmitting, and responding to followup requests from FDA for supplemental information in our estimate. We expect to receive approximately 100 510(k) submissions via eSTAR per year and estimate that eSTAR submissions will each require 40 hours to complete. In addition, based on a recent review of submissions, we estimate 1,906 summary cover sheets will be received annually. We assume 30 minutes are needed to complete the summary cover sheet. We further estimate that 9 respondents will submit information pertaining to a request for recognition of a voluntary standard and that the activity requires an average of 1 hour. We also account for a one-time setup burden of 5 minutes for an estimated 80 new eSTAR users annually.

As a result of adding burden previously included under OMB control numbers 0910–0616 (submission certification element) and 0910–0767 (custom device exemptions), we have adjusted our burden upward. We have also made nominal adjustments on individual provisions to reflect expected fluctuations in submissions. Cumulatively, these actions result in an overall increase of 3,671 hours and a corresponding increase of 4,210 responses annually.

Dated: June 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12489 Filed 6–9–23; 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 Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

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 General Medical Sciences Special Emphasis Panel; Centers of Biomedical Research Excellence (COBRE Phase 1).

Date: July 20, 2023.

Time: 9:00 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: Jason M. Chan, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of General Medical Sciences, 45 Center Drive, MSC 6200, Bethesda, Maryland 20892, 301–594–3663, *jason.chan2@nih.gov*.

Information is also available on the Institute's/Center's home page: *www.nigms.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

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

Dated: June 7, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–12457 Filed 6–9–23; 8:45 am]

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