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

21 CFR section and activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response (in hours)	Total hours
Total Hours (§ 1107.1(c))					732
Section 905(j)(1)(A)(ii) of the FD&C Act: If exemption granted, report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3)					
Abbreviated report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3)	1217	1	1217	3	3,651
Total Hours (section 905(j)(1)(A)(ii)) of the FD&C Act					3,651
Total Hours Exemptions From Substantial Equivalence Requirements					23,871

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

FDA estimates that we will receive 812 exemption requests under § 1107.1(b) for 24 hours per response including EA for a total of 19,488 hours. Since an EA is required for each § 1107.1(b) (Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request), the burden per response for EAs (12 hours) has been combined with the 12 hours for an SE request for a total of 24 hours per response.

FDA further estimates that we will receive 244 submissions requiring additional information in support of the initial exemption request, and it is expected that it will take an average of 3 hours to prepare the additional information for a total of 732 hours.

FDA estimates that 1,217 respondents will prepare 1,217 responses and each response will take approximately 3 hours to prepare, as required by section 905(j)(1)(A)(ii) of the FD&C Act, for a total of 3,651 hours.

This collection of information requires a manufacturer to submit a report at least 90 days prior to making an introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product. Section 905(j)(1)(A)(ii) of the FD&C Act states that if an exemption has been requested and granted, the manufacturer must submit to FDA a report that demonstrates that the tobacco product is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the FD&C Act, and all the modifications are covered by exemptions granted by the Secretary under section 905(j)(3). FDA estimates the total hours for exemptions from Substantial Equivalence Requirements will be 23,871 hours.

FDA's estimates are based on full analysis of economic impacts and information gathered from other FDA-regulated products. Based on a review of the currently approved information collection, we have made no adjustments to our burden estimate.

Dated: September 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19913 Filed 9–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Forms for Use With Applications to the Maternal and Child Health Bureau Research and Training Grants, OMB No. 0906—New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate below or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than November 13, 2018.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Forms for Use with Applications to the Maternal and Child Health Bureau Research and Training Grants, OMB No. 0906–xxxx—New.

Abstract: HRSA currently utilizes the National Institute of Health's (NIH) Biographical Sketch and Public Health Service (PHS) Inclusion Enrollment forms (0925–0001) for HRSA's SF424 Research & Related application package research grants. In order to update the forms to meet HRSA's needs, HRSA plans to remove the NIH-specific references and obtain its own OMB control number for the collection of this information.

Need and Proposed Use of the Information: HRSA's Maternal and Child Health Bureau (MCHB) plans to modify the Biographical Sketch and the

PHS Inclusion Enrollment Form in slightly different ways in order to meet the needs of its own research and training grant programs. In MCHB's research grant programs, the modified Biographical Sketch form will be used by applicants to summarize the qualifications of each key personnel on their proposed research team, and grant reviewers will use this information to assess the capabilities of the research team to carry out the research project as planned. Monitoring inclusion enrollment is one important component of ensuring demographic diversity (race, ethnicity, and gender) among research study participants in MCHB's research grant portfolio. MCHB's modified PHS Inclusion Enrollment form will be used by applicants to summarize their expected population of research study participants at the time of submission of their proposal, and it will also be used for Enrollment Reporting during the annual Noncompeting Continuation Award.

Likely Respondents: Respondents are applicants to MCHB's research programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Biographical Sketch for MCHB research grant applicants ..	200	5	1,000	2.0	2,000
PHS Inclusion Enrollment form for MCHB research grant applications	200	1	200	0.5	100
Total	400	.....	1,200	.....	2,100

HRSA specifically requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–19903 Filed 9–12–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 General Medical Sciences Special Emphasis Panel; Review of NIGMS Support of Competitive Research (SCORE) Award Applications.

Date: November 14, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Nina Sidorova, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN.22, Bethesda, MD 20892–6200, 301–594–3663, *sidorova@nigms.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 10, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–19915 Filed 9–12–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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: NIGMS Initial Review Group; Training and Workforce Development Subcommittee—C; Review of MARC/RISE Applications.

Date: October 29–30, 2018.

Time: 8:00 a.m. to 5:00 p.m.