consider comments on the proposed order (section 515(b) of the FD&C Act, as amended by FDASIA).

Under the FD&C Act, FDA's call for PMAs must, among other things, contain an opportunity for interested persons to request a change in the classification of the device based on new information (section 515(b)(2) of the FD&C Act). After consideration of comments on the proposed order and findings, FDA must either: (1) Finalize the call for PMAs by issuing an administrative order requiring approval of a PMA and publishing in the **Federal Register** findings with respect to: (i) The degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed product development protocol and (ii) the benefit to the public from the use of the device; or (2) publish a notice in the **Federal Register** terminating the proceeding and initiate a reclassification proceeding based on new information (section 515(b)(3) of the FD&C Act, as amended by FDASIA; see section 513(e) of the FD&C Act).

The FD&C Act, as amended by FDASIA, now requires the use of administrative orders, rather than rulemaking, when FDA calls for PMAs for a preamendments device remaining in class III (section 515(b) of the FD&C Act, as amended by FDASIA).

FDA refers to a device that was not in commercial distribution before the 1976 Amendments as a postamendments device. Postamendments devices are classified automatically into class III by statute, without any rulemaking process (section 513(f)(1) of the FD&C Act). A postamendments device remains in class III and is subject to the PMA requirements unless and until: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II via the De Novo classification process (see section 513(f)(2) of the FD&C Act); or (3) FDA issues an order finding the device to be substantially equivalent to a predicate device that does not require the filing of a PMA (see section 513(i) of the FD&C Act).

FDA may initiate, or the manufacturer or importer of a device may petition for, the reclassification of a postamendments device classified into class III by operation of law (section 513(f)(3) of the FD&C Act). This FDA-initiated reclassification process consists of a proposed reclassification order, optional panel consultation, and a final reclassification order published in the **Federal Register** following consideration of comments and any panel recommendations or comments (§ 860.134(c) (21 CFR 860.134(c))). The reclassification order may, as appropriate, establish special controls to provide reasonable assurance of the safety and effectiveness of the device (§ 860.134(d)).

Under the 1976 Amendments, Congress classified all those devices previously regulated as new drugs into class III (generally referred to as transitional devices). Under the FD&C Act, FDA may initiate, or the manufacturer or importer of a device may petition for, the reclassification of a transitional device remaining in class III (section 520(l)(2) of the FD&C Act (21 U.S.C. 360j(l)(2)). The process for reclassification of transitional devices initiated by FDA is detailed in 21 CFR ?860.136(c). This process consists of a proposed reclassification order, optional panel consultation, and a final reclassification order published in the **Federal Register** following consideration of comments and any panel recommendations or comments.

In the **Federal Register** of September 7, 2021 (86 FR 50132), 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]

21 CFR section; information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 860.123; supporting data for reclassification petitions	6	1	6	497	2,982

[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 since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: December 22, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–28305 Filed 12–28–21; 8:45 am]

BILLING CODE 4164–01–P917

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0906–0066—Extension]

Agency Information Collection Activities: Proposed Collection: Public Comment Request SHIP COVID–19 Testing and Mitigation Program Data Collection

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

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 should be received no later than February 28, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to 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 Samantha Miller, the acting HRSA Information Collection Clearance Officer at (301) 443–9094.

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

Information Collection Request Title: Small Rural Hospital Improvement Program (SHIP) COVID–19 Testing and Mitigation Program Data Collection OMB No. 0906–0066—Extension.

Abstract: The American Rescue Plan Act of 2021 (Pub. L. 117–2) provided one-time funding for awards that will be carried out under Section 711 of the Social Security Act (42 U.S.C. 912(b)(5)). The SHIP is requesting an extension of an information collection request. State grantees will improve health care in rural areas by using the funding to provide support to eligible rural hospitals to increase COVID–19 testing efforts, expand access to testing in rural communities, and expand the range of mitigation activities.

Need and Proposed Use of the Information: The terms and conditions for this program specify that, ''hospitals will be required to report on the number of tests provided and categories in which the funding is spent.'' The data will allow HRSA to ensure SHIP COVID–19 recipients are meeting the terms and conditions of their funding, while providing HRSA with information on the effectiveness of funds distributed through this program.

Likely Respondents: The respondents will be hospital staff and designated Representatives, and State Office of Rural Health Staff.

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 and 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 ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of respondents per respondent	Total responses	Average burden per response (in hours)	Total burden hours
SHIP COVID–19 Testing and Mitigation Data Reporting.	1,540 ..... Number of unique organizations funded through the program.	6 ..... Reported on a quarterly basis during the 18 month program or until the end of the public health emergency (whichever is first).	9,240	.25	2,310 Total hours spend on responses for all funded organization over a 2-year period.
	1,540	.....	9,240	.....	2,310

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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–28268 Filed 12–28–21; 8:45 am]

BILLING CODE 4165–15–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 cooperative agreement applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the cooperative agreement applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders C Study Section Translational Neural, Brain, and Pain Relief Devices.

Date: February 8–9, 2022.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Diana M. Cummings, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Neurological Disorders and Stroke, NIH, NSC, 6001 Executive Blvd., Suite 3208, Bethesda, MD 20892, *cummingsdi@ninds.nih.gov*.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; NSD–C Member Conflict Special Emphasis Panel.

Date: February 15, 2022.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Diana M. Cummings, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Neurological Disorders and Stroke, NIH, NSC, 6001 Executive Blvd., Suite 3208, Bethesda, MD 20892, *cummingsdi@ninds.nih.gov*.

(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: December 22, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–28277 Filed 12–28–21; 8:45 am]

BILLING CODE 4140–01–P