TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
ANADA	356v	20	1	20	159	3,180
Phased review with administrative ANADA	356v	6	5	30	31.8	954
Biowaiver request for soluble powder oral dosage form product, using same formulation/manufacturing process approach	N/A	1	1	1	5	5
Biowaiver request for soluble powder oral dosage form product, using same API/solubility approach	N/A	5	1	5	10	50
Biowaiver request for Type A medicated article, using same formulation/manufacturing process approach	N/A	2	1	2	5	10
Biowaiver request for Type A medicated article, using same API/solubility approach	N/A	5	1	5	20	100
Total				63		4,299

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

We base our estimates on our records of generic animal drug applications. We estimate that we will receive 26 ANADA submissions per year over the next 3 years and that 6 of those submissions will request phased review. We estimate that each applicant that uses the phased review process will have approximately five phased reviews per application. We estimate that an applicant will take approximately 159 hours to prepare either an ANADA or the estimated five ANADA phased review submissions and the administrative ANADA. Our estimates of the burden of biowaiver requests for generic soluble powder oral dosage form products and Type A medicated articles differ based on the type of product and the basis for the request, as shown in table 1. We estimate that an applicant will take between 5 and 20 hours to prepare a biowaiver request.

Our estimated burden for the information collection reflects an overall increase of 695 hours and a corresponding increase of 12 responses. Based on a review of the information collection since our last request for OMB renewal, the increase in the burden hours estimate is attributable to an increase in the number of respondents submitting generic drug applications.

Dated: March 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; SHIP COVID–19 Testing and Mitigation Program Data Collection, OMB No. 0906–0066—Extension

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than April 18, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the acting HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: 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 Small Rural Hospital Improvement Program (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.

A 60-day Notice published in the **Federal Register**, 86 FR 74095 (December 29, 2021). There were no public comments.

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 responses 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 spent on responses for all funded organization over a 2-year period.
Total	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. 2022–05717 Filed 3–17–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; The Stem Cell Therapeutic Outcomes Database OMB No. 0915–0310—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for an 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). Before 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 May 17, 2022.

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 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 request collection title for reference.

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database OMB No. 0915–0310—Revision.

Abstract: The Stem Cell Therapeutic and Research Act of 2005, Public Law (Pub. L.) 109–129, as amended by the TRANSPLANT Act of 2021, Public Law 117–15 (the Act), provides for the collection and maintenance of human blood stem cells for the treatment of patients and for research. The Act requires the Secretary to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using an electronic format. HRSA's Health Systems Bureau has established the Stem Cell Therapeutic Outcomes Database (SCTOD), one component of the C.W. Bill Young Cell Transplantation Program (Program) which necessitates certain electronic record keeping and reporting requirements to perform the functions related to hematopoietic stem cell transplantation (HCT) under contract to HHS. Data is collected from transplant centers by the Center for International Blood and Marrow Transplant Research and is used for ongoing analysis of transplant outcomes to improve the treatment, survival and quality of life for patients who may benefit from cellular therapies. Over time, there is an expected increase in the information reported as the number of transplants performed annually increases, and survivorship after transplantation improves. Similarly, because of ongoing rapid evolution in transplant indications, methods to establish diagnoses, disease prognostic factors, treatments provided before HCT, methods to determine donor matching, and transplantation techniques, the Program anticipates incremental changes in information collected by the SCTOD to reflect current clinical care and facilitate statistical modeling throughout the approval period to fulfill the requirements of the Program. Such small incremental changes will not significantly affect the burden.

Need and Proposed Use of the Information: Per statutory responsibilities, the collection of information outlined in the ''Total Estimated Annualized Burden Hours'' section below is needed to collect, analyze, and publish stem cell transplantation related data including patient outcomes data and provide the Secretary with an annual report of transplant center-specific survival data. The proposed revisions of this information collection reflect the most up-to-date medical evidence while simultaneously reducing HCT facility burden. Revisions fall into several categories: Consolidating questions, implementing interactive requests (electronic check boxes, check all that apply, and pull-down menus) to reduce data entry time, adding necessary information fields, adding clarity to information requests and removing items no longer clinically significant (*e.g.,* drugs). These revisions also