Containers—'Dose Banding'.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 201 have been approved under OMB control number 0910–0572; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15523 Filed 7–20–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0906–xxxx–New]

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Healthy Start Evaluation and Capacity Building Support

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, as described below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than September 19, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N–39, 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) 443–1984.

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

Information Collection Request Title: Healthy Start Evaluation and Capacity Building Support, OMB No. 0906–xxxx–New.

Abstract: The National Healthy Start Program, authorized by 42 U.S.C. 254c–8 (§ 330H of the Public Health Service Act) and funded through HRSA's Maternal and Child Health Bureau, has the goal of reducing disparities in maternal and infant health. The program began as a demonstration project with 15 grantees in 1991 and has expanded over the past 3 decades to 101 grantees across 35 states, Washington, DC, and Puerto Rico. Healthy Start grantees operate in communities with rates of infant mortality at least 1.5 times the U.S. national average, or with high rates of other adverse perinatal outcomes (*e.g.,* low birthweight, preterm birth). Grantees may also qualify for the program if their project areas meet other relevant criteria (*e.g.,* high rates of diabetes, obesity, or tobacco use during pregnancy; low utilization of prenatal care in the first trimester; no utilization of prenatal care during pregnancy) that demonstrate disparities in health outcomes for pregnant women in their communities. Healthy Start programs are located in communities that are geographically, racially, ethnically, and linguistically diverse. Healthy Start covers services during the perinatal period (before, during, after pregnancy) and follows the women, infants, and fathers/partners through 18 months after the end of the pregnancy. The Healthy Start program uses a life course approach that includes women's health, family health and wellness, and community/population health.

HRSA seeks to implement a mixed-methods evaluation to assess the effectiveness of the program on individual, organizational, and community-level outcomes. Data collection instruments will include the (1) Healthy Start Program Survey, (2) Healthy Start Network Survey, (3) Healthy Start Participant Survey, and (4) Healthy Start Stakeholder Interview Guide. These instruments have been specifically designed to be non-duplicative. Using previously approved content, the Healthy Start Program Survey is designed to collect information on the experiences of all 101 grantee programs related to program infrastructure, services/activities, participants, community partnerships, new maternal and fatherhood initiatives, and health equity. The information collected in the survey will allow the Healthy Start grantees to better assess risk, identify needed services, provide appropriate follow-up activities to program participants, and improve overall service delivery and quality.

The two other surveys and interview guide will be administered to a subset of 15 grantees, their community partners, and participants. The Healthy Start Network Survey focuses on understanding the participation of members in the Healthy Start Community Action Networks (CANs) [1] and collaborations within the CANs to improve maternal, infant, and family outcomes within the Healthy Start communities. Results from the survey will help the Healthy Start programs and their CANs identify areas of strength and opportunities for further collaborations, understand how well the CAN members are working together to serve women and their families, and whether they are supporting the programs in addressing the participants' greatest needs. The Healthy Start Participant Survey is designed to collect information about the experiences of the Healthy Start participants with the program and assess whether the programs are meeting their needs. The Healthy Start grantees can use this

[1] A CAN is an existing, formally organized partnership of organizations and individuals. The CAN represents consumers and appropriate agencies which unite in an effort to collectively apply their resources to the implementation of one or more common strategies to achieve a common goal within that project area.

information to identify areas to strengthen the services provided to the participants. The Healthy Start Stakeholder Interview Guide is designed to collect more in-depth information about the Healthy Start services, the new maternal health and fatherhood initiatives, CAN activities, and activities developed to improve the Healthy Start benchmarks and achieve health equity.

Need and Proposed Use of the Information: The purpose of the data collection instruments is to obtain consistent information across all grantees about Healthy Start, its operations and outcomes. The data will be used to (1) conduct ongoing performance monitoring of the program; (2) provide credible and rigorous evidence of program effect on outcomes; (3) meet program needs for accountability, programmatic decision-making, and ongoing quality assurance; and (4) strengthen the evidence base and identify best and promising practices for the program to support sustainability, replication, and dissemination of the program.

Likely Respondents: Respondents will include project directors and staff for the Healthy Start Program Survey, members of the CANs for the Healthy Start Network Survey, program participants for the Healthy Start Participant Survey, and program and administrative staff for the Healthy Start Stakeholder Interview Guide.

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 utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing 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. The total number of responses was multiplied by the average burden per response and summed to produce the total annualized burden hours, which is estimated to be 600 hours. A break-down of these hours is detailed 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
Healthy Start Program Survey	101	1	101	1.00	101
Healthy Start Network Survey	[2] 600	1	600	0.33	198
Healthy Start Participant Survey.	[3] 750	1	750	0.25	188
Healthy Start Stakeholder Interview Guide	[4] 150	1	150	0.75	113
Total	1,601		1,601		600

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. 2022–15570 Filed 7–20–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal for the Advisory Commission on Childhood Vaccines

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA), HHS is hereby giving notice that the charter for the Advisory Commission on Childhood Vaccines (ACCV) has been renewed. The effective date of the renewed charter is July 21, 2022.

FOR FURTHER INFORMATION CONTACT: CDR George Reed Grimes, M.D., MPH, Designated Federal Officer, Health Systems Bureau, HRSA, 5600 Fishers Lane, 08N186A, Rockville, Maryland 20857; (301)443–6634; or *ACCV@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACCV provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under 2119 of the Public Health Service Act (the Act) (42 U.S.C. 300aa-19), as enacted by Public Law 99–660, and as subsequently amended. The ACCV advises the Secretary on issues related to implementation of the National Vaccine Injury Compensation Program. Other activities of the ACCV include: recommending changes in the Vaccine Injury Table at its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 of the Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying federal, state, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b) of the Act; advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; consulting on the development or revision of Vaccine Information Statements; and recommending to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the National Vaccine Injury Compensation Program.

The renewed charter for the ACCV was approved on July 1, 2022. The filing

[2] This is the maximum number of responses for this data collection instrument.

[3] Ibid.

[4] Ibid.