for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Eileen Wu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3472, Silver Spring, MD 20993–0002, 301–796–2345, *eileen.wu@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is establishing a public docket to collect comments on a draft document entitled ''Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff.'' Title IX, section 915 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) added a new section 505(r) to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(r)), requiring FDA to prepare a summary analysis of the adverse drug reaction reports received for a drug by 18 months after approval or after use of the drug by 10,000 individuals, whichever is later. The analysis includes identification of any new risks not previously identified, potential new risks, or known risks reported in unusual number.

The Cures Act (Pub. L. 114–255) was enacted on December 13, 2016, and has the goal of advancing medical product innovation, as well as ensuring patient access to safe and effective treatments as soon as possible. Section 3075 of the Cures Act amended section 505(r)(2)(D) of the FD&C Act to eliminate the requirement for summary analyses for drugs as required by FDAAA. In place of the summary analyses, section 3075 amended section 505(r)(2)(D) of the FD&C Act to include the requirement that FDA make publicly available on its internet website best practices for drug safety surveillance activities for drugs approved under section 505 of the FD&C Act or section 351 of the Public Health Service Act (PHS Act).

Section 3075 of the Cures Act also amended section 505(k)(5) of the FD&C Act to strike ''bi-weekly screening'', as required by FDAAA, and insert ''screenings''; it also added the requirement that FDA make publicly available on its internet website guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System.

The draft document entitled ''Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff'' sets forth risk-based principles by which FDA conducts ongoing postmarketing safety surveillance for drug and biological products to address the Cures Act requirements. Although section 3075 of the Cures Act only references drugs approved under section 505 of the FD&C Act or section 351 of the PHS Act, the draft document additionally provides a high-level discussion regarding other products, including over-the-counter monograph, compounded, and homeopathic drug products. The draft document also includes a high-level overview of other data sources, tools, and methods, as well as drug safety surveillance activities that extend beyond use of the Adverse Event Reporting System (and its successors). These additional topics are included to provide context and a general overview of FDA's safety surveillance process. FDA is seeking public comment on the draft best practices document before it begins work on the final version, which will be made publicly available.

II. Electronic Access

Persons with access to the internet may obtain the draft document entitled ''Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff'' at *https://www.fda.gov/media/130216/download.*

Dated: November 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24332 Filed 11–6–19; 8:45 am]

BILLING CODE 4164–01–P

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; Information Collection Request Title: Healthy Start Evaluation and Quality Improvement, OMB No. 0915–0338—Revision

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

ACTION: Notice.

SUMMARY: In compliance with 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.

DATES: Comments on this ICR should be received no later than December 9, 2019.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Healthy Start Evaluation and Quality Improvement. OMB No. 0915–0338—Revision.

Abstract: The National Healthy Start Program, funded through HRSA's Maternal and Child Health Bureau (MCHB), has the goal of reducing racial and ethnic disparities in infant mortality and other adverse perinatal outcomes. The program began as a demonstration project with 15 grantees in 1991 and since then has expanded to 101 grantees serving communities in 34 states, Washington, DC, and Puerto

Rico. Healthy Start grantees serve communities with high rates of poor perinatal outcomes, including infant mortality at least 1.5 times the U.S. national average. These communities are often low-income and in geographically, racially, ethnically, and linguistically diverse areas. Healthy Start offers services during the perinatal period (before, during, and after pregnancy) and the program works with women, infants, and families through the first 18 months after birth. The Healthy Start program uses four approaches to reduce infant mortality through individual services and community support to women, infants, and families: (1) Improve women's health, (2) improve family health and wellness, (3) promote systems change, and (4) assure impact and effectiveness. Over the past few years, MCHB has sought to implement a uniform set of data elements for monitoring and conducting an evaluation to assess grantees' progress towards these program approaches. Under the current OMB approval, the data collection instruments for this evaluation include the following: The National Healthy Start Program Survey; Community Action Network Survey; Healthy Start Site Visit Protocol; Healthy Start Participant Focus Group Protocol; and six client-level screening tools: (1) Demographic Intake Form, (2) Pregnancy Status/History, (3) Preconception, (4) Prenatal, (5) Postpartum, and (6) Interconception/ Parenting.

In this proposed revision, MCHB plans to retain the client-level tools, and to eliminate the National Healthy Start Program Survey, Community Action Network Survey, Healthy Start Site Visit Protocol, and Healthy Start Participant Focus Group Protocol instruments. These instruments have been removed to streamline this data collection activity for the evaluation. For the six client-level tools, MCHB plans to consolidate these into three forms: (1) Background, (2) Prenatal, and (3) Parent/Child. These tools have been revised based on the public comments received during the 60-day comment period. The purpose of these changes is to consolidate items that are duplicated across the forms. In addition to consolidating questions across tools, many individual items have been eliminated or in some cases reworded in order to focus the evaluation more clearly on individual and programmatic progress on performance measures. This will shorten the revised instruments, center them more clearly on program improvement, and decrease the number of personal/sensitive questions.

In addition to the elimination, consolidation, and rewording of several items, questions designed to increase efficiency and accuracy in reporting have been added. Specifically, many of the grantees' annual reporting requirements require calculations based on infants' birth dates, estimated due dates, dates enrolled in the Healthy Start program, trimester in which certain health-related activities occurred, and so on. These revised tools include the information necessary to make these calculations so that annual aggregate reporting will be based on individual client-level data. This will increase accountability, efficiency, and accuracy in terms of the clients served as well as reduce overall burden on the grantees by streamlining reporting systems.

A 60-day notice was published in the **Federal Register** on January 31, 2019, vol. 84, no. 21, pp. 753–754. There were 16 public comments.

Need and Proposed Use of the Information: The purpose of the revised data collection instruments will be to assess grantee and client-level progress towards meeting Healthy Start program performance measures. The data will be used to conduct ongoing performance monitoring of the program; thus, meeting program needs for accountability, programmatic decision-making, and ongoing quality assurance.

Likely Respondents: Respondents include pregnant women and non-pregnant women of reproductive age who are served by the Healthy Start program as well as any of their spouses/ partners or other caregivers who are participating in receiving Healthy Start services.

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. Compared to the versions submitted for the 60-day approval process in January, estimated burden hours have increased somewhat as a result of implementing the feedback provided in public comments during the 60-day comment period. 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
Background	*55,550	1	55,550	.50	27,775
Prenatal	*30,300	1	30,300	.17	5,151
Parent/Child	*30,300	1	30,300	.42	12,726
Total	116,150	.....	116,150	.....	45,652

*All participants (55,550) complete the Background form, and a subset of these same individuals (30,300) also complete the Prenatal or Parent/Child forms, for a total of 116,150 responses.

Maria G. Button,

Director, Executive Secretariat.

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