determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Michelle Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993–0002, 240–402–0374, *Michelle.Weiner@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but it must be made prior to FDA's approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, is the subject of NDA 020711, held by GlaxoSmithKline LLC, and initially approved on May 14, 1997. ZYBAN is indicated as an aid to smoking cessation treatment.

ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Yichang Humanwell Pharmaceutical Co., Ltd. submitted a citizen petition dated April 18, 2022 (Docket No. FDA–2022–P–0614), under 21 CFR 10.30, requesting that the Agency determine whether ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27647 Filed 12–20–22; 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 Information Collection Request Title: Healthy Start Evaluation and Capacity Building Support, OMB No. 0906–xxxx—New

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 must be received no later than January 20, 2023.

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 301–594–4394.

SUPPLEMENTARY INFORMATION:

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 (section 330H of the Public Health Service Act) and funded through HRSA, 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 in the program 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 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.

A 60-day notice was published in the **Federal Register**, 87 FR 43535 (July 21, 2022). There were no public comments.

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	[1] 600	1	600	0.33	198
Healthy Start Participant Survey	[2] 750	1	750	0.25	188
Healthy Start Stakeholder Interview Guide	[3] 150	1	150	0.75	113
Total	1,601		1,601		600

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

[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.

[2] Ibid.
[3] Ibid.

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. 2022–27698 Filed 12–20–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Nurse Corps Loan Repayment Program; OMB No. 0915–0140 Extension

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 January 20, 2023.

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 301–594–4394.

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

Information Collection Request Title: Nurse Corps Loan Repayment Program (Nurse Corps LRP), OMB No. 0915–0140—Extension.

Abstract: The Nurse Corps LRP assists in the recruitment and retention of professional Registered Nurses (RNs), including Advanced Practice Registered Nurses (APRNs), by decreasing the financial barriers associated with pursuing a nursing education. RNs in this instance include APRNs (*e.g.,* nurse practitioners, certified registered nurse anesthetists, certified nurse-midwives, and clinical nurse specialists) dedicated to working at eligible health care facilities with a critical shortage of nurses (*i.e.,* a Critical Shortage Facility) or working as nurse faculty in eligible, accredited schools of nursing. The Nurse Corps LRP provides loan repayment assistance to these nurses to repay a portion of their qualifying educational loans in exchange for full-time service at a public or private Critical Shortage Facility or in an eligible, accredited school of nursing.

A 60-day notice published in the **Federal Register** on September 29, 2022, vol. 87, No. 188; pp. 59106–07. There were no public comments.

Need and Proposed Use of the Information: Individuals must submit an application in order to participate in the program. The application asks for personal, professional, educational, and financial information required to determine the applicant's eligibility to participate in the Nurse Corps LRP. This information collection is used by the Nurse Corps program to make award decisions about Nurse Corps LRP applicants and to monitor a participant's compliance with the program's service requirements. The Nurse Corps LRP is requesting an extension and is seeking to use the previously approved forms.

Likely Respondents: Professional RNs or APRNs who are interested in participating in the Nurse Corps LRP, and official representatives at their service sites.

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 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
Nurse Corps LRP Application *	7,100	1	7,100	2.00	14,200
Authorization to Release Information Form **	7,100	1	7,100	.10	710
Employment Verification Form **	7,100	1	7,100	.10	710
Disadvantaged Background Form	450	1	450	.20	90
Confirmation of Interest Form	500	1	500	.20	100
Total for Applicants	22,250		22,250		15,810

* The burden hours associated with this instrument account for both new and continuation applications. Additional (uploaded) supporting documentation is included as part of this instrument and reflected in the burden hours.

** The same respondents are completing these instruments.