4027, Attn: August 30, 2021 ACIP Meeting.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the *https://www.regulations.gov* suitability policy will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

In accordance with 41 CFR 102–3.150(b), less than 15 calendar days' notice is being given for this meeting due to the exceptional circumstances of the COVID–19 pandemic and rapidly evolving COVID–19 vaccine development and regulatory processes. The Secretary of Health and Human Services has determined that COVID–19 is a Public Health Emergency.

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MS–H24–8, Atlanta, GA 30329–4027; Telephone: 404–639–8367; Email: *ACIP@cdc.gov.*

Public Participation

Written Public Comment: The docket will close on August 30, 2021. Written comments must be received on or before August 30, 2021.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–20478 Filed 9–21–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0921]

B. Braun Medical, Inc.; Withdrawal of Approval of Abbreviated New Drug Application of Hydroxyethyl Starch

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of abbreviated new drug application (ANDA) BA110013/0032 for 6 Percent Hydroxyethyl Starch 130/0.4 in 0.9 Percent Sodium Chloride Injection in EXCEL® Plastic Container, held by B. Braun Medical, Inc. B. Braun Medical, Inc., requested in writing that the Agency's approval of the application be withdrawn because the drug is no longer being marketed and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of October 22, 2021.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, 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: B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109, has requested that FDA withdraw approval of ANDA BA110013/0032, pursuant to § 314.150(c) (21 CFR 314.150(c)), because the drug is no longer being marketed. By its request, B. Braun Medical Inc. has also waived its opportunity for a hearing. Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

Application No.	Proprietary name
ANDA BA 110013/0032	6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride Injection in EXCEL® Plastic Container.

Therefore, approval of the application listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of October 22, 2021. Introduction or delivery for introduction into interstate commerce for products without an approved new drug application or ANDA violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). The drug product that is listed in the table above that is in inventory on October 22, 2021 may continue to be dispensed until the inventory has been depleted or the drug product has reached its expiration date or otherwise becomes violative, whichever occurs first.

Dated: September 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–20511 Filed 9–21–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3326]

Reauthorization of the Biosimilar User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is hosting a virtual public meeting to discuss proposed recommendations for the reauthorization of the Biosimilar User Fee Act (BsUFA) for fiscal years (FYs) 2023 through 2027. The BsUFA authorizes FDA to collect user fees to support the process for the review of biosimilar biological product applications. The current legislative authority for BsUFA expires in September 2022. At that time, new legislation will be required for FDA to continue collecting user fees in future fiscal years. Following discussions with the regulated industry and consultations with public stakeholders, the Federal Food, Drug, and Cosmetic Act (FD&C Act) directs FDA to publish the recommendations for the reauthorized program in the **Federal Register**, hold a meeting at which the public may present its views on such recommendations, and provide for a period of 30 days for the public to provide written comments on such recommendations. FDA will then consider such public views and comments and revise such recommendations, as necessary.

DATES: The public meeting will be held on November 2, 2021, from 9 a.m. to 12 p.m. Eastern Time, and will be held by webcast only. Submit either electronic or written comments on this public

meeting by December 2, 2021. See **SUPPLEMENTARY INFORMATION** for registration date and information.

ADDRESSES: Registration to attend the meeting and other information can be found at *https://bsufaiii-finalpublicmeeting.eventbrite.com.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 2, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 2, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–3326 for ''Reauthorization of the Biosimilar User Fee Act; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Emily Ewing, Center for Drug Evaluation and Research, Food and Drug Administration, 240–402–0196, *Emily.Ewing@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing a virtual public meeting to discuss proposed recommendations for the reauthorization of BsUFA, the legislation that authorizes FDA to collect user fees to support the process for the review of biosimilar biological product applications. The current authorization of the program (BsUFA II) expires in September 2022. Without new legislation, FDA will no longer be able to collect user fees for future FYs to fund the process for the review of biosimilar biological product applications. Section 744I(f)(2) of the FD&C Act (21 U.S.C. 379j–53(f)(2)) requires the Agency perform the following actions after holding negotiations with regulated industry members: (1) Present recommendations to the relevant Congressional committees; (2) publish recommendations in the **Federal Register**, (3) provide a period of 30 days for the public to provide written comments on the recommendations; (4) hold a meeting at which the public may present its views; and (5) after consideration of public views and comments, revise the recommendations as necessary.

This notice, the 30-day comment period, and the public meeting will satisfy some of these requirements. After the public meeting, we will revise the recommendations as necessary and present our proposed recommendations to the Congressional committees.

The purpose of the meeting is to hear the public's views on the proposed recommendations for the reauthorized program (BsUFA III). The following information is provided to help potential meeting participants better understand the history and evolution of the BsUFA program and the status of the proposed BsUFA III recommendations.

II. What is BsUFA and what does it do?

BsUFA is a law that authorizes FDA to assess and collect fees from drug companies that submit marketing applications for certain biosimilar biological products. BsUFA was originally enacted in 2012 as the Biosimilar User Fee Act under the Food and Drug Administration Safety and Innovation Act (FDASIA, Pub. L. 112–144) for a period of 5 years. In 2017, BsUFA was renewed for 5 more years under the FDA Reauthorization Act of 2017 (FDARA, Pub. L. 115–52).

BsUFA is intended to provide additional revenues so that FDA can hire staff, improve systems, and continue a well-managed biosimilar

biological product review process to make biosimilar biological product therapies available to patients sooner without compromising review quality or FDA's high standards for safety, efficacy, and quality. As part of FDA's agreements with industry during prior BsUFA authorizations, the Agency agreed to certain performance and procedural goals and other commitments. These goals apply to the process for the review of biosimilar biological product applications, including biosimilar biological product development meetings, review of applications and supplements, and other review activities. FDA's web page ''Biosimilar User Fee Amendments'' provides more information about BsUFA, including the statutory text of FDARA, the BsUFA commitment letter, ''Biosimilar Authorization Performance Goals and Procedures Fiscal Years 2013 through 2017'' (BsUFA Commitment Letter), key **Federal Register** documents, BsUFA-related guidances, BsUFA user fee rates, performance reports, and financial reports. The Agency's ''Biosimilar User Fee Amendments'' web page is available at *https://www.fda.gov/industry/fda-user-fee-programs/biosimilar-user-fee-amendments.*

With the current authorization of BsUFA II under FDARA, FDA implemented a review program (''the Program'') to promote the efficiency and effectiveness of the first cycle review process. The Program allows for additional communication between the FDA review team and applicants of biosimilar biological products, including mid-cycle communications and late-cycle meetings, while adding 60 days to the review clock to provide for this increased interaction and to address review issues. BsUFA II also includes commitments to advance development of biosimilar biological products through further clarification of the regulatory pathway that permits a biosimilar biological product to be licensed under section 351(k) of the Public Health Service Act, and to enhance capacity for biosimilar guidance development, reviewer training, and timely communication. More information on these commitments can be found in the BsUFA II Commitment Letter at *https://www.fda.gov/media/100573/download.*

As part of the current authorization, FDA established an independent fee structure and fee amounts to improve program funding predictability, stability, and administrative efficiency. The new structure established a BsUFA target revenue based on BsUFA program costs and updated the overall fee structure and related financial mechanisms. The agreement also included commitments to enhance management of user fee resources through the development of a resource capacity planning capability and third-party evaluation of program resource management, management of the carryover balance, along with the publication and annual update of a 5-year financial plan.

The current authorization also includes several commitments to improve the hiring and retention of critical review staff through modernization of FDA's hiring system, augmentation of hiring staff capacity and capabilities, creation of a dedicated function focused on staffing the program, reporting on hiring metrics, and a comprehensive and continuous assessment of hiring and retention. A list of the deliverables developed to meet BsUFA II commitments is available on the FDA web page *https://www.fda.gov/industry/biosimilar-user-fee-amendments/completed-bsufa-ii-deliverables.*

III. Proposed BsUFA III Recommendations

In preparing the proposed recommendations to Congress for BsUFA reauthorization, FDA conducted discussions with regulated industry members, as required by the law. We began the BsUFA reauthorization process by publishing a notice in the **Federal Register** requesting public input on the reauthorization and announcing a public meeting that was held on November 19, 2020. The meeting included presentations by FDA and a series of panels with representatives of different stakeholder groups, including patient advocates, consumer groups, regulated industry members, health professionals, and academic researchers. The materials from the meeting, including a transcript and webcast recording, can be found at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/public-meeting-reauthorization-biosimilar-user-fee-act-bsufa-11192020-11192020.*

Following the November 2020 public meeting, FDA conducted negotiations with regulated industry from March 2021 through June 2021. As directed by Congress, FDA posted minutes of these meetings on its web page at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iii-fiscal-years-2023-2027.*

The proposed enhancements for BsUFA III address many of the top priorities identified by public stakeholders, regulated industry, and FDA. While some of the proposed enhancements are new, many either build on successful enhancements or refine elements from the existing program. The enhancements are proposed in the following areas: Supplemental applications, meeting management, best practices in communication between FDA and sponsors, inspections and alternative tools, interchangeable biosimilar biological product development, regulatory science, finance, hiring and retention, and information technology. The full text of the proposed BsUFA III Commitment Letter can be found on the Agency's web page ''BsUFA III: Fiscal Years 2023—2027,'' available at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iii-fiscal-years-2023-2027.* Each significant new or modified enhancement is described briefly below:

A. Original and Resubmitted Supplemental Biosimilar Biological Product Applications

To expedite the review of supplemental biosimilar biological product applications, FDA proposes to establish new supplement categories, timelines, and performance goals. New review timelines range from 3 to 10 months, depending on the content and category of the supplement submission. Certain supplements for safety labeling updates and labeling updates to add or remove an indication that do not contain efficacy data sets would have shorter review timelines than supplements in other categories. These enhancements are described in section I.A.2 of the proposed BsUFA III Commitment Letter.

B. Meeting Management Goals

To improve overall meeting management, FDA proposes to modify the Biosimilar Initial Advisory (BIA) meeting, create a new Type 2a meeting, and modify the timing of Type 4 meeting background packages. FDA would not require the submission of preliminary comparative analytical data for a BIA meeting. The new Type 2a meeting would allow for quicker discussion on a narrow set of issues (*e.g.,* often one but no more than two issues) involving no more than three review disciplines or divisions. Traditional Type 2 meetings under BsUFA II would be renamed to Type 2b meetings in BsUFA III. Under this proposal, the Type 4 meeting background package may be submitted up to 14 calendar days after FDA receives the meeting request. There would also be a new followup opportunity to pose clarifying questions after meetings or a written-response-

only communication. These enhancements are described in section I.H of the proposed BsUFA III Commitment Letter.

C. Promoting Best Practices in Communication Between FDA and Sponsors During Application Review

To enhance communication with sponsors during biosimilar biologic product application review, FDA proposes to update relevant guidances, our Manual of Policies and Procedures, and our Standard Operating Procedures and Policies regarding best practices in communication. FDA would utilize lessons learned from BsUFA II to update the relevant documents, as appropriate. The details of this enhancement are found in section II.A of the proposed BsUFA III Commitment Letter.

D. Enhancing Inspection Communication and Alternative Tools

To facilitate the timely development of biosimilar biological products and their availability to patients, FDA proposes to notify sponsors of certain pre-license inspections and to issue guidance on FDA's thinking on the use of alternative tools to assess manufacturing facilities beyond the COVID–19 pandemic. These enhancements are described in section II.B of the proposed BsUFA III Commitment Letter.

E. Advancing Development of Biosimilar Biological-Device Combination Products Regulated by CDER and CBER

Sponsors employ Use-Related Risk Analyses (URRA) studies to identify the need for risk mitigation strategies and to design a human factors (HF) validation study. Based on a URRA, a sponsor may propose that a HF validation study is not needed to support the safe and effective use of a biosimilar biologic-device combination product. FDA proposes establishing new procedures for the review of URRAs along with performance goals. Human factors studies are conducted to evaluate the user interface of a biosimilar biologic-device combination product to eliminate or mitigate use-related hazards that may affect the safe and effective use of the combination product. Over the past decade, more combination products have been developed to deliver therapeutics via different routes of administration (*e.g.,* parenteral, inhalation) with complex engineering designs. HF validation protocols are reviewed during the investigational new drug application stage with the goal towards developing a final finished combination product that supports the marketing application. To achieve this objective, FDA proposes updating the procedures for HF validation study protocols, along with a new performance goal. These enhancements are described in section II.C of the proposed BsUFA III Commitment Letter.

F. Advancing Development of Interchangeable Biosimilar Biological Products

FDA proposes a focused effort in BsUFA III to further advance the development of safe and effective interchangeable biosimilar biological products. This effort would address current needs, prospectively identify future needs, and incorporate the following components: (1) Research leveraging the BsUFA III Regulatory Science Pilot Program; (2) foundational guidance development; and (3) stakeholder engagement involving a scientific workshop on the development of interchangeable biosimilar biological products to help identify future needs. Associated with this workshop, FDA would issue draft and final strategy documents outlining FDA's actions to facilitate the development of interchangeable biosimilar biological products. The details of this enhancement are described in section II.D of the proposed BsUFA III Commitment Letter.

G. Regulatory Science

To enhance regulatory decision-making and facilitate science-based recommendations in areas foundational to biosimilar biological product development, FDA proposes to pilot a regulatory science program broadly applicable to biosimilar and interchangeable biological product development, with project goals not specific to a product or product class. The pilot program would focus on two demonstration projects: (1) Advancing the development of interchangeable biosimilar biological products and (2) improving the efficiency of biosimilar biological product development. As part of these demonstration projects, FDA proposes to engage stakeholders in a public meeting to review the progress of the demonstration projects and to solicit input of future priorities. An interim report would be issued prior to the public meeting, and a final summary report of outcomes from the pilot program would be posted on FDA's website. Within 12 months of completing the demonstration projects, FDA would publish a comprehensive strategy document outlining actions FDA will take to facilitate the development of biosimilar and interchangeable biological products. These enhancements are described in section II.E of the proposed BsUFA III Commitment Letter.

H. Continued Enhancement of User Fee Resource Management

FDA is committed to ensuring the sustainability of BsUFA program resources and to enhancing the operational agility of the BsUFA program. FDA proposes to build on the financial enhancements included in BsUFA II and continue activities in BsUFA III to ensure optimal use of user fee resources and the alignment of staff to workload through the continued maturation and assessment of the Agency's resource capacity planning capability. This proposal would also include an independent assessment of the resource capacity planning capability. FDA proposes to continue activities to promote transparency of the use of financial resources in support of the BsUFA program through annual public meetings, publishing a 5-year financial plan along with annual updates, and additional reporting in the annual BsUFA Financial Report. These enhancements are described in section III of the proposed BsUFA III Commitment Letter.

I. Information Technology

FDA proposes to establish and progress a data and technology modernization strategy that provides FDA's strategic direction for current and future state data-driven regulatory initiatives. Additionally, FDA would advance the use of cloud-based technology to modernize the Electronic Submission Gateway to support greater data submission bandwidth and storage in the BsUFA program. These enhancements are described in section V of the proposed BsUFA III Commitment Letter.

J. Enhancements to Fee Mechanisms for Increased Predictability, Stability, and Efficiency

The proposed BsUFA III agreement continues to build on the resource capacity planning capability established in BsUFA II and continues financial transparency initiatives. In addition, to manage financial risks in the program, BsUFA III proposes to enhance the operating reserve adjustment mechanism to provide for a defined minimum and maximum required amount of operating reserves. The proposed minimum amount is equivalent to 10 weeks of operating reserves and the maximum amount is equivalent to 21 weeks of available operating reserves to be maintained each year. The annual maximum

amount of available operating reserves would be phased in over the first 3 years of BsUFA III (33 weeks in fiscal year 2023, 27 weeks in fiscal year 2024, and 21 weeks in fiscal year 2025). BsUFA III also proposes to add a strategic hiring and retention adjustment to ensure FDA has the funding necessary to provide for the costs of retaining and hiring highly qualified scientific and technical staff for the process for the review of biosimilar biological product applications under BsUFA. This strategic hiring and retention adjustment would add $150,000 to the base revenue amount each fiscal year during BsUFA III.

K. Impact of BsUFA III Enhancements on User Fee Revenue

To implement the proposed enhancements for BsUFA III, funding for a cumulative total of 15 FTE staff is proposed to be phased in over the course of BsUFA III. The new funding would be phased in as follows:

- $4,428,886 for fiscal year 2023
- $320,569 for fiscal year 2024

IV. Public Meeting Information

A. Purpose and Scope of the Meeting

The virtual public meeting will include a presentation by FDA and an industry panel. For members of the public who would like to make verbal comments on the proposed enhancements, there will be a public comment period at the end of the meeting (see instructions below). We will also provide an opportunity for individuals to submit written comments to the docket before and after the meeting.

B. Participating in the Public Meeting

Registration: Registration is optional and not required to attend this virtual public meeting. However, registering will allow FDA to provide you with email updates if any meeting details change. If you wish to register, you can do so at *https://bsufaiii-finalpublicmeeting.eventbrite.com.*

Opportunity for Verbal Public Comment: Those who register online will receive a confirmation email that includes a link to a request form to make a verbal public comment at the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request time jointly. All requests to make a public comment during the meeting must be received by October 19, 2021, 11:59 p.m. Eastern Time. Depending on the number of requests, we will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and will select and notify participants by October 26, 2021. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: The Zoom Webinar ID for this public meeting is 161 047 8285. The webcast link for this public meeting can be found here: *https://fda.zoomgov.com/j/1610478285?pwd=MG1lN2hrYzBVTGhsd1F2eVhwZG1DQT09.* The link above should allow you to enter the webinar directly. If Zoom asks for a passcode, please use the case-sensitive passcode below.

Case-Sensitive Passcode for Zoom Webinar: S9d&fx

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). Transcripts of the meeting will be available on the FDA web page *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iii-fiscal-years-2023-2027* approximately 30 days after the meeting.

Dated: September 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–20432 Filed 9–21–21; 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: Bureau of Primary Health Care—Program Management Resource Compendium, 0906–XXXX, New

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. 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 October 22, 2021.

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 HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Bureau of Primary Health Care—Program Management Resource Compendium, OMB No. 0906–XXXX, New.

Abstract: The Program Management Resource Compendium project will encompass an historical analysis of HRSA's Bureau of Primary Health Care (BPHC), as well as a historical analysis of the Health Center Program, performed by federal contractors. Dating from the founding of the initial community health centers in the mid-1960s up to the present time, the analysis will consider the evolution and critical milestones of BPHC and the Health Center Program based on documentary research and interviews with individuals with historical knowledge of the Health Center Program and the health center movement.

A 60-day notice published in the **Federal Register** (86 FR 30962 (June 10, 2021). There were no public comments.

Need and Proposed Use of the Information: The information gathered through interviews will be combined with information drawn from documentary research to inform the historical analysis. The results of the analysis will be presented in communication products for an internal audience, as well as products for an external audience. The goals of the project are to increase awareness of the Health Center Program management