

or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than October 28, 2026.

A. Federal Reserve Bank of New York (Keith Goodwin, Head of Bank Applications) 33 Liberty Street, New York, New York 10045-0001. Comments can also be sent electronically to Comments.applications@ny.frb.org:

1. *Gullace Generation Family Trust, Christopher Matthew Gullace as trustee, both of Delray Beach, Florida*; to acquire voting shares of Greater Rochester Bancorp Inc., and thereby indirectly acquire voting shares of Genesee Regional Bank, both of Rochester, New York.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026-20886 Filed 10-9-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-D-2581]

Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products: Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products: Questions and Answers." This guidance provides answers to commonly asked questions from applicants and other interested parties regarding postapproval manufacturing changes made to biosimilar and interchangeable biosimilar products licensed under the Public Health Service Act (PHS Act). This guidance finalizes the draft guidance of the same title issued on July 23, 2024.

DATES: The announcement of the guidance is published in the **Federal Register** October 13, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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-2024-D-2581 for "Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products: Questions and Answers." Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Ashley Boam, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm 4192, Silver, Spring, MD 20993-0002, 301-796-6341, cder-quality-policy@fda.hhs.gov; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products: Questions and Answers." This guidance provides answers to commonly asked questions from applicants and other interested parties regarding postapproval manufacturing changes (referred to as "manufacturing changes" throughout this notice) made to biosimilar and interchangeable biosimilar products licensed under section 351(k) of the PHS Act (42 U.S.C. 262(k)). FDA is publishing this guidance to fulfill the commitment made in the 2022 reauthorization of the Biosimilar User Fee Act (BsUFA III, Title IV—Fees Relating to Biosimilar Biological Products, Pub. L. 117-180) for fiscal years 2023 through 2027. This guidance is intended to inform applicants of the nature and type of information, for different reporting categories, that

applicants should provide to support manufacturing changes to licensed biosimilar and licensed interchangeable biosimilar products. The recommendations in this guidance are intended to be consistent with the principles outlined in the International Council for Harmonisation (ICH) guidance for industry entitled "Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process" (June 2005) (ICH Q5E), available at <https://www.fda.gov/media/71489/download>.

In the **Federal Register** of September 20, 2021 (86 FR 52154), FDA published the notice of availability of a guidance for industry entitled "Questions and Answers on Biosimilar Development and the BPCI Act" ("Q&A biosimilar development guidance"), available at <https://www.fda.gov/media/119258/download> (revised March 10, 2026; see 91 FR 11555). The intent of that guidance is to provide answers to commonly asked questions from applicants and other interested parties to, among other things, facilitate the development of proposed biosimilar and proposed interchangeable biosimilar products under the Biologics Price Competition and Innovation Act of 2009. Postapproval manufacturing changes to biosimilar products is the subject of Q&A I.20 in the Q&A biosimilar development guidance. FDA did not provide recommendations for interchangeable biosimilar products in Q&A I.20 because FDA had limited experience regarding manufacturing changes for licensed interchangeable biosimilar products when that guidance originally issued. FDA has since determined that the principles that apply to manufacturing changes for biosimilar products are relevant to interchangeable biosimilar products. Recognizing that this discussion merits more exploration than a single Q&A item can facilitate, FDA has developed this guidance, which elaborates on the topic of manufacturing changes made to both licensed biosimilar and licensed interchangeable biosimilar products.

FDA may withdraw a Q&A that was previously in a guidance if FDA determines that the issue described in the Q&A is addressed in another guidance. The finalization of this guidance reflects FDA's current thinking on the topic of postapproval manufacturing changes to biosimilar and interchangeable biosimilar products and supersedes the recommendations provided in Q&A I.20 in the Q&A biosimilar development guidance. Therefore, at this time, FDA is also withdrawing Q&A I.20 from the Q&A biosimilar development guidance. Since

this guidance is being issued as a standalone guidance, it does not retain the same numbering as the Q&A biosimilar development guidance.

This guidance finalizes the draft guidance entitled "Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products: Questions and Answers" issued on July 23, 2024 (89 FR 59740). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: (1) further aligning recommendations in the guidance with the principles in ICH Q5E; (2) clarifying recommendations for leveraging comparative analytical assessment data from an original 351(k) biologics license application (351(k) BLA); and (3) clarifying edits to Q&A 4 on the nature and type of information that FDA recommends to support approval of a supplement for a dosage form or a strength that has not previously been licensed under the 351(k) BLA. Additional editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products: Questions and Answers." 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.

FDA considered the applicability of Executive Order 14192, per OMB guidance in M-25-20, and finds this action to be neither an E.O. 14192 regulatory action nor an E.O. 14192 deregulatory action.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in 21 CFR 201.56 and 201.57 relating to the content and format requirements for labeling of drug and biological products have been approved under OMB control number 0910-0572. The collections of information in 21 CFR parts 210 and 211 relating to current good manufacturing practice requirements have been approved under OMB control

number 0910–0139. The collections of information in section 351(k) of the PHS Act relating to biosimilar and interchangeable biosimilar product applications have been approved under OMB control number 0910–0718. The collections of information in section 351(a) of the PHS Act and 21 CFR part 601 relating to biologics license applications (BLA) have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the 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>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20817 Filed 10–9–26; 8:45 am]

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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; 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 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 November 12, 2026.

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:* Healthy Start Evaluation and Quality Improvement.

OMB No. 0915–0338—Revision
Abstract: The National Healthy Start Program, authorized by 42 U.S.C. 254c–8 (§ 330H of the Public Health Service Act), seeks to improve maternal and infant health outcomes and reduce infant mortality and other adverse perinatal outcomes. Established in 1991 as a demonstration project with 15 grantees, the program has expanded to 114 grantees serving communities in 37 states, the District of Columbia, and Puerto Rico. Healthy Start operates in communities experiencing disproportionately high rates of infant mortality and adverse birth outcomes and provides outreach, case management, care coordination, health education, and other supportive services to women, infants, children up to 18 months of age, fathers, and families. Healthy Start programs tailor services to meet the unique needs of their communities. Serving as comprehensive care hubs, they provide outreach, one-on-one case management, care coordination, clinical services (e.g., behavioral health care, midwifery care), and individual and group-based health and parenting education. Programs work across health care and social service systems to help pregnant women and families access prenatal and postpartum care, mental health therapy, substance use treatment, nutrition and breastfeeding support, transportation, and other essential resources that contribute to healthier pregnancies and improved infant and maternal health outcomes.

Over the past few years, HRSA has sought to implement a uniform set of data elements for monitoring and conducting an evaluation to assess grantees' progress towards these program goals. Under the previously approved OMB collection, the data collection instruments for the program's reporting requirements include four

participant-level screening tools: (1) Demographic, (2) Background Information, (3) Prenatal, and (4) Parent/Child forms. The primary purpose of this information collection request is to reinstate the four data collection forms included in the information collection that expired on September 30, 2026. HRSA is proposing a limited number of minor revisions to the forms for the purposes described below.

HRSA also anticipates seeking OMB approval for additional revisions to the information collection in advance of the 2029–2034 Healthy Start grant cycle. Consistent with recommendations from the U.S. Government Accountability Office (GAO), HRSA plans to revise certain Healthy Start measures to better align with measures used by other Maternal and Child Health Bureau programs, including the Title V Maternal and Child Health Services Block Grant and the Maternal, Infant, and Early Childhood Home Visiting Program. GAO also recommended that changes to Healthy Start measures and related data collection materials be completed prior to the start of a new grant cycle. To inform the future revisions, HRSA plans to solicit input from internal and external interested parties beginning in late 2026 as part of the process for updating the data collection forms for the 2029–2034 grant cycle. HRSA has also compiled comments received in response to the 60-day notice for consideration in developing the future information collection request.

In this reinstatement with change, HRSA plans to retain the participant-level tools as approved by OMB in 2020 and updated in 2024, with minor changes to: (1) clarify instructions, (2) update select response options to improve accuracy in reporting, and (3) add fields to capture the month of infant birth and/or death. These revisions are intended to improve the quality and usability of the data collection instruments and enhance the accuracy of tracking infant birth and death outcomes. The revised instructions were developed in response to grantee feedback and are expected to reduce confusion and improve consistency in form completion.

The 60-day notice described four categories of proposed changes to the data collection instruments. Following publication of that notice, HRSA further reviewed the proposed revisions and determined that certain changes should be deferred. Specifically, HRSA is no longer proposing changes to separate response options to reflect current program priorities and has narrowed the proposed updates to select response