U.S. FOOD & DRUG ADMINISTRATION

WELCOME

We will begin the meeting promptly at 9:00am.

U.S. FOOD & DRUG ADMINISTRATION

Public Meeting on the Recommendations and Proposed Enhancements for BsUFA IV

Monday, October 26, 2026

Danielle Villata

Center for Drug Evaluation and Research, FDA

Meeting Moderator, Office of Program and Strategic Analysis

Submit your public comments by November 25!

You can access the docket via:

- FDA's public meeting webpage

  (https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-reauthorization-biosimilar-user-fee-act-bsufa-10262026)

- Directly through the Federal Register

  (https://www.federalregister.gov/documents/2026/09/25/2026-19660/reauthorization-of-the-biosimilar-user-fee-act-public-meeting-request-for-comments)

AGENDA

- Welcome and Introduction
- Opening Remarks
- BsUFA Background and Reauthorization Process
- Program: Proposed Enhancements
- Finance: Proposed Enhancements
- Break
- Public Stakeholder Perspectives
- Public Comment
- Closing Remarks

Opening Remarks

Grace Graham

Deputy Commissioner for Policy, Legislation, and International Affairs

BsUFA Background and Reauthorization Process

Andrew Kish

Center for Drug Evaluation and Research, FDA

Director, Office of Program and Strategic Analysis

BsUFA Background

BsUFA is now over 10 years old

- The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) directed FDA to develop recommendations for a user fee program for 351(k) applications for FY 2013 – FY 2017.
- In 2011-2012, there were no marketing applications or products on the market, established drug development process or history related to biosimilar biological products.
- After consultation with regulated industry and public stakeholders, FDA transmitted recommendations to Congress on January 13th, 2012. The Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 included the first authorization of BsUFA.
- BsUFA is in its 15th year. Since its creation, BsUFA facilitated the approval of 89 biosimilar biological products for the American public.

BsUFA was established in 2012 to speed delivery of safe and effective biosimilar biological products

BsUFA I (2013 to 2017):

- Referenced PDUFA fee amounts and included fees for products in the development phase in order to generate fee revenue to support FDA's review work during development and enable sponsors to have meetings with FDA early in development.
- Introduced predictable timelines and review process performance goals, primarily modeled on PDUFA, that increased over the course of BsUFA I.

BsUFA II (2018 – 2022):

- Established an independent, efficient user fee structure based on program costs.
- Implemented a review program ("the Program") to promote the efficiency and effectiveness of the first review cycle and minimize the number of review cycles necessary for biosimilar approval.
- Added commitments to assess the Program, clarify the regulatory pathway, and enhance staff capacity.

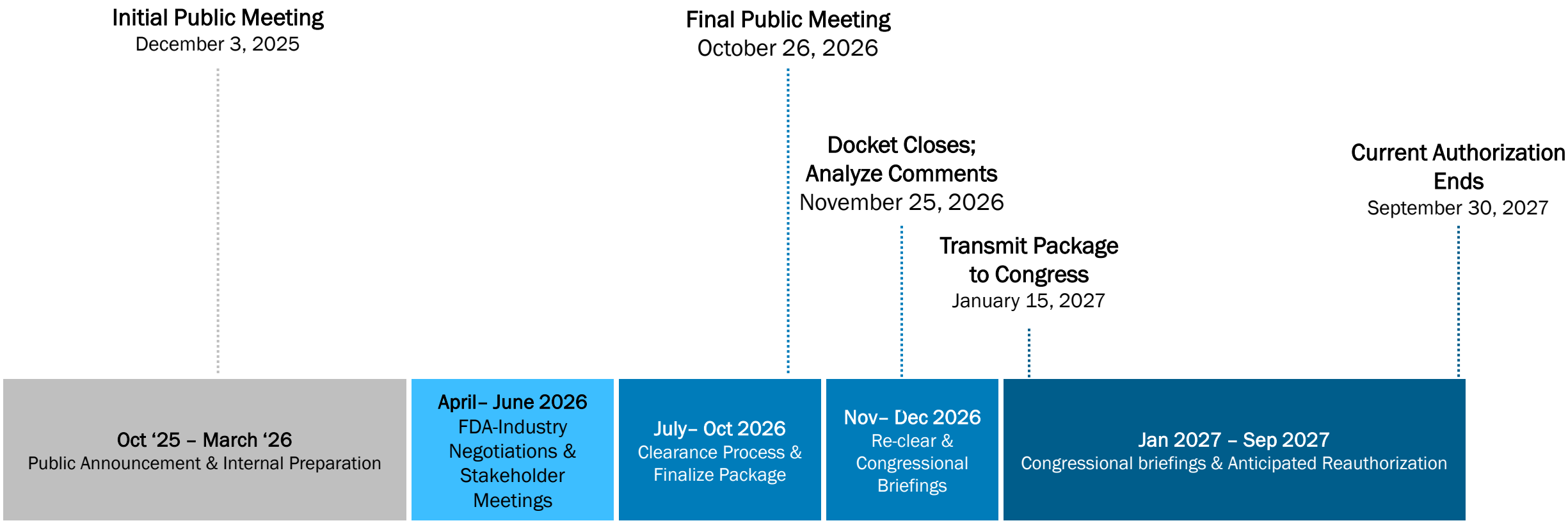
BsUFA was established in 2012 to speed delivery of safe and effective biosimilar biological products

BsUFA III (2023 - 2027):

- Introduced new supplement types and expedited review timelines
- Introduced timelines for review of Use-Related Risk analysis and Human Factors studies
- Introduced new pilot regulatory science program to enhance regulatory decision-making and facilitate science-based recommendations
- Introduced focused effort to advance the development of interchangeable products

Reauthorization Process Overview

Overview of Reauthorization Process



BsUFA reauthorization involves significant consultation with stakeholders.

BsUFA REAUTHORIZATION and REPORTING REQUIREMENTS.

(f) REAUTHORIZATION.—

(1) CONSULTATION.*—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of human drug applications for the first 5 fiscal years after fiscal year 2027, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with— (A) the Committee on Energy and Commerce of the House of Representatives; (B) the Committee on Health, Education, Labor, and Pensions of the Senate; (C) scientific and academic experts; (D) health care professionals; (E) representatives of patient and consumer advocacy groups; and (F) the regulated industry.*

(2) PRIOR PUBLIC INPUT.—*Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—*

(A) publish a notice in the Federal Register requesting public input on the reauthorization; (B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a); (C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and (D) publish the comments on the Food and Drug Administration's Internet Web site.

(3) PERIODIC CONSULTATION.*—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).*

(4) UPDATES TO CONGRESS. —*The Secretary, in consultation with regulated industry, shall provide regular updates on negotiations on the reauthorization of this subpart to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.*

(5) PUBLIC REVIEW OF RECOMMENDATIONS.*—After negotiations with the regulated industry, the Secretary shall— (A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph; (B) publish such recommendations in the Federal Register; (C) provide for a period of 30 days for the public to provide written comments on such recommendations; (D) hold a meeting at which the public may present its views on such recommendations; and (E) after consideration of such public views and comments, revise such recommendations as necessary.*

(6) TRANSMITTAL OF RECOMMENDATIONS.—*Not later than January 15, 2027, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.*

(7) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—*The Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry, not later than 30 days after each such negotiation meeting..*

(B) CONTENT.*—The minutes described under subparagraph (A) shall summarize, in sufficient detail, any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.*

This public meeting is one of the last steps in the reauthorization process.

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Overview of Recommendations

Highlights of BsUFA IV

- Prioritizes an America First approach to drug development
  - Limits the small business waiver to U.S.- based companies
- Increases review process efficiency
  - Streamlines supplement categories and reduced review times
  - Introduces process to enable Agency to act on applications upon exclusivity expiration
  - Establishes a process for FDA to work past the goal date to address late-arising, resolvable issues
- Advances a lifecycle approach to addressing manufacturing issues
- Maintains critical support for technical and scientific staff
- Revises the fee structure to incentivize sponsor submission practices that aim to increase review efficiency
- Enhances regulatory and financial transparency

Program:
Performance Enhancements

Sarah Yim

Center for Drug Evaluation and Research, FDA

Director, Office of Therapeutic Biologics and Biosimilars (OTBB)

Mustafa Ünlü

Center for Drug Evaluation and Research, FDA

Director, Biosimilar Regulatory Review Staff, OTBB

Review Efficiency

Revised Supplement Categories

- Replaces BsUFA III supplement categories (Categories A-F) with two categories that correspond with either 4- or 6- month timelines

Increased Efficiency for Submission of Initial Pediatric Study Plans (iPSPs)

- Commits to publishing a biosimilar-specific iPSP template and make it available for public comment
- Commits to revising (as needed) and finalizing the template following the comment period and issuing corresponding guidance

Prioritization of Feedback on IND Protocols

- Commits to prioritizing the review of protocols submitted for clinical studies intended to form a primary role for a biologics license application, to ensure applicants receive feedback on critical questions prior to study initiation

Review Efficiency

Imminent Action (IA)

- Establishes a process for FDA to work 60 days past the goal date to address late-arising, resolvable issues (e.g., updates to the reference product labeling and/or REMS) in the biosimilar program

Combination Products

- Expands Type 2b meeting description to allow sponsors to request review of use-related risk analysis (URRA), comparative analysis (CA) or human factor (HF) study protocols
- Establishes HF validation study protocol review goals
- Commits to publishing guidance on alternative approaches to comparative use human factor studies (CUHFs)

Meeting Management

- Removes the biosimilar initial advisory (BIA) meeting and modifies the Type 2b meeting description
- Modifies language to enable Industry to request written response only (WRO) option for all BsUFA meeting types
- Modifies language to enable Industry to use follow up opportunity to seek advice on questions that were raised during the review cycle but could not be addressed until after the meeting

Review Efficiency

New Target Action Dates

- Establishes a process for (1) assigning a new target action date and (2) communicating with sponsors in the event the FDA misses a goal date

Regulatory Science Pilot Program

- Sunsets regulatory science program at the end of BsUFA III

Provisional Determinations

- Establishes a process and corresponding timelines for FDA to manage and take action on applications placed in a provisional determination status, which occurs when the application otherwise meets applicable licensure standards but cannot be approved until blocking exclusivity expires

- Commits to publishing guidance on provisional determinations process

BLA Revocation and Reissuance

- Establishes defined timeframe for revoking and reissuing licenses when a sponsor informs the FDA of an expected license transfer

Sau (Larry) Lee

Center for Drug Evaluation and Research, FDA

Deputy Director, Office of Pharmaceutical Quality

CMC Facility Lifecycle Program

Aims to mitigate the occurrence of deficiencies that, if unaddressed, may lead to multiple review cycles

CMC Facility Pre-submission Meeting

(For Original BLAs, Including CMC Supplements Related to Manufacturing Facilities)

- Introduces a new option for a single CMC Facility Pre-submission meeting to discuss manufacturing facilities for a proposed application submission to facilitate their readiness before a facility evaluation and inspection

Post-Pre-License Inspection (PLI) Meeting

(For Original BLAs, not Including Supplements)

- Introduces a new post inspection meeting, when needed, to discuss inspection findings that may impact application approval and corrective actions that may address identified approvability issues
- Allows FDA to extend the goal date upon receiving a meeting request package for a Post-PLI meeting when an extension would permit review of the new information provided, and there is a reasonable likelihood that review of the new information provided could address outstanding facility deficiencies relevant to the application and lead to approval in the current review cycle

CMC Facility Lifecycle Program (Continued)

CMC Facility Post-Action Meeting

- Includes a meeting for applications that receive a complete response action in part due to manufacturing facilities to discuss and gain understanding of those facility deficiencies that should be corrected before the application can be approved

Guidance for Industry

- Commits to publishing draft guidance describing the implementation of this CMC Facility Lifecycle Program

CMC Facility Lifecycle Workshop and Third-Party Assessment

- Commits to an assessment and workshop focused on the implementation of the new BsUFA IV CMC enhancements and the impact of those enhancements on facility readiness and reduction in facility deficiencies

Andrew Kish

Center for Drug Evaluation and Research, FDA

Director, Office of Program and Strategic Analysis

Assessment of the Program, Pre-INDs, INDs, and BLAs

- Commits to an assessment of review processes, outcomes, and FDA-sponsor communications that will provide recommendations to help FDA and sponsors increase the effectiveness and efficiency of key review processes, communications, and materials and limit first cycle complete responses and goal extensions.

Industry Comments

Ryan Kaat

Pharmaceutical Research and Manufacturers of America

Assistant General Counsel, Law

Julianna Reed

The Biosimilars Forum

Executive Director

Giuseppe Randazzo

Association for Accessible Medicines

Senior Vice President of Sciences and Regulatory Affairs

Steve Berman

Biotechnology Innovation Organization

Vice President, Science and Regulatory Affairs Strategy

Finance:
Proposed Enhancements

Kristopher Hoover

Office of Finance, Budget, and Acquisitions, FDA

Data Scientist, Resource Capacity Planning Branch

Financial Transparency

Five-Year Financial Plan

- Continues the commitment to publish a 5-year financial plan and update the plan annually
- Updates the topics to be included in the 5-year financial plan and annual updates to focus on reporting on shared services and an index of financial- and personnel-related reporting to help external audiences navigate data provided in various reports

Annual Financial Report

- Updates the topics to be included in the annual financial report to Congress to (1) include new reporting on the operating reserve tracking, reserving, and reporting (OR TRR), and (2) enhance reporting on personnel compensation and benefits as well as operating expenses

Technical Staff Meeting

- Introduces a new technical staff meeting each year for FDA and Industry to discuss BsUFA finances and commits to publishing minutes from this meeting

Proposed Statutory Changes: Revenue Framework

- Reduces the operating reserve adjustment maximum balance from 21 weeks to 18 weeks
- Introduces the operating reserve tracking, reserving, and reporting (OR TRR), which tracks funds in the operating reserve set aside for restaffing and retaining scientific and technical expertise in the BsUFA program, and annual reporting on the OR TRR
- Modifies the capacity planning adjustment (CPA) so that it will not be available until FDA restaffs to certain level of scientific and technical expertise
- Sunsets the Strategic Hiring and Retention Adjustment at the end of BsUFA III, as intended

Proposed Statutory Changes: Fee Structure

- Introduces three-tier approach with no differential for applications with clinical or comparative efficacy study (CES) data
  - Full Fee: BLA application (no differentiation on clinical or CES data)
  - Half Fee: Secondary BLA for the same drug substance, that ***IS NOT*** submitted on the same day
  - No Fee: Secondary BLA for the same drug substance, that ***IS*** submitted on the same day
- Eliminates Biosimilar Biological Development Program (BPD) fee
- Updates the eligibility for a small business waiver to only U.S.-based companies

Transparency in FDA Hiring and Retention of Review Staff

- Continues the public webpages describing quarterly hiring updates and net CDER and CBER hires
- Commits to updates on restaffing of the BsUFA program, including prioritizing staffing for review functions and specific BsUFA IV enhancements (e.g., Supplement Review, Facility Lifecycle, and Provisional Determinations)

Industry Comments

Sean Hilsher

Pharmaceutical Research and Manufacturers of America

Senior Director, Science and Regulatory Advocacy

Julianna Reed

The Biosimilars Forum

Executive Director

Scott Kuzner

Association for Accessible Medicines

Senior Director of Sciences and Regulatory Affairs

Steve Berman

Biotechnology Innovation Organization

Vice President, Science and Regulatory Affairs Strategy

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BREAK

Check the chat for our restart time.

Submit your public comments by November 25!

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Public Stakeholder Perspectives

Ravi Harapanhalli

Amneal Pharmaceuticals

Public Comment

Closing Remarks

Andrew Kish

Center for Drug Evaluation and Research, FDA

Director, Office of Program and Strategic Analysis

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THANK YOU