

BsUFA IV Updates

BsUFA IV Negotiation team (Industry)

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BsUFA History: Four Authorization Cycles

BsUFA Origins

- The Biologics Price Competition and Innovation Act (BPCIA, March 2010) created the abbreviated 351(k) licensure pathway
- No biosimilar had yet been licensed in the U.S.; March 2015 first approved biosimilar
- Sponsors needed early, repeated FDA scientific advice to design development programs for a new pathway
- BsUFA I - FY2013–2017

What BsUFA established

- Industry fees in exchange for FDA review performance goals and a formal biosimilar development (BPD) meeting program
- 90% of original 351(k) BLAs reviewed within 10 months; since BsUFA II, measured from the 60-day filing date
- BsUFA fees now fund roughly 61% of FDA's biosimilar review activities, and the program has supported nearly 90 approvals

Why it matters: Biosimilars generated $25.4 billion in U.S. savings in 2025 and $81.6 billion since 2015, across nearly 3.8 billion days of patient therapy.

BsUFA History: Four Authorization Cycles

Program	Enacted	Fiscal years	Defining features
BsUFA I	July 9, 2012 FDASIA (Pub. L. 112-144, Title IV)	FY2013–2017	First biosimilar user fee program; BPD fees paid during development for access to BIA and BPD Type 1–4 meetings; review goals phased up to 90% within 10 months
BsUFA II	Aug. 18, 2017 FDA Reauthorization Act (Pub. L. 115-52)	FY2018–2022	"Program" for enhanced review transparency (review clock starts after 60-day filing period, mid-cycle and late-cycle communications); simplified fee structure with an annual program fee
BsUFA III	Sept. 30, 2022 FDA User Fee Reauthorization Act (Pub. L. 117-180, Title IV)	FY2023–2027	Supplement Categories A–F with expedited timelines; Type 2a meeting and follow-up opportunity; URRA and HF protocol review goals; regulatory science pilot; interchangeability guidances
BsUFA IV (proposed)	Pending; legislation needed before Sept. 30, 2027	FY2028–2032	To be discussed TODAY

Why it matters: Biosimilars generated $25.4 billion in U.S. savings in 2025 and $81.6 billion since 2015, across nearly 3.8 billion days of patient therapy.

What BsUFA IV Targets: Four Objectives

FDA's framing: the proposed enhancements match advances in science and industry, add processes for efficiency and communication, take a lifecycle approach to manufacturing issues, and enhance transparency.

1 Modernize the Program

Supplement categories tied to review burden; predictable review of user-interface submissions; BIA meeting and BPD fees retired.

Result: Review timelines that match the work involved

2 Improve Efficiency and Communication

Provisional determination and RFA process; imminent action; new target action dates; WRO option for every meeting type.

Result: Fewer avoidable CRLs and on-time action at exclusivity expiry

3 Take a Lifecycle Approach to Facilities

Facility readiness guidance plus CMC pre-submission, post-PLI, and post-action meetings.

Result: Fewer facility-driven complete responses

4 Enhance Transparency

Third-party assessment of review and communication; personnel set-aside; expanded financial and hiring reporting.

Result: Accountability for restaffing and review performance

Source: FR notice, Docket FDA-2015-N-3326 (Sept. 25, 2026), § III; grouping of enhancements by AAM

Fee Reforms, Financial Accountability, Reduced Cost of Development

1 No Overall Increase in Program Funding Target & Increased Financial Accountability

Agreement that existing BsUFA revenues are sufficient to support proposed program enhancements and associated staffing needs, avoiding any increase in target program revenue.

Agreement includes:

- Operating Reserve Tracking, Reserving, and Reporting (OR TRR),
- greater transparency into FDA hiring and UF spending
- increased accountability for ensuring fee revenues are used to support review capacity

2 Application Fee Reforms and Reduced Financial Burden for Biosimilar Sponsors

Agreement:

- elimination of BPD fee
- new application fee framework

Submission scenario	Application fee
First 351(k) BLA	100%
Qualifying* additional BLA submitted by the same sponsor on a later day	50%
Qualifying* additional BLA submitted by the same sponsor on the same day	0% (BOGO)

* BLA must contain substantially the same drug substance information to qualify for the fee reduction.

BSUFA IV: MEETING PROGRAM CHANGES

Eliminates BIA meetings

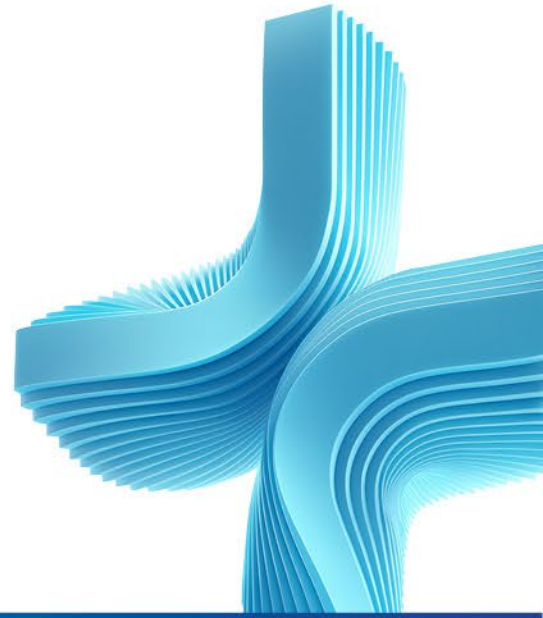
Initial engagement moves into the BPD Type 2b meeting

Removes BPD fee

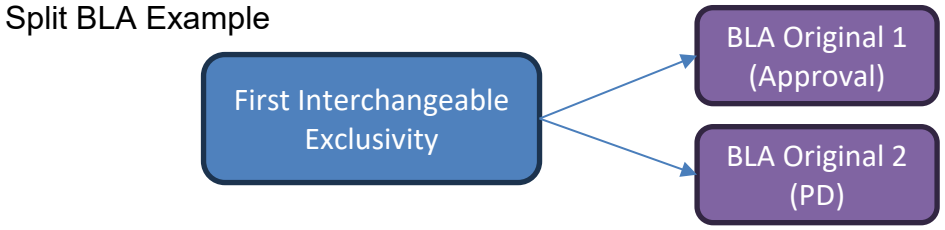
No fee for BPD meetings

Expands written-response and follow-up opportunities

Additional opportunities for off-cycle communication and clarifications to WROs and meeting minutes



Provisional Determinations (PDs) & Requests for Approval (RFAs)





Vehicle for Changes Other than RFAs

- When the product is covered by both approved and PD status BLAs, submit a supplement to the approved BLA
- When the product is only covered by a PD status BLA, submit an amendment (a "PD amendment")

Timeline for Changes Other than RFAs

- Supplements: Governed under BsUFA supplement procedure
- PD Amendments:
  - FDA will strive to act within a clock comparable to a supplement, but no formal goal date
  - In limited circumstances, FDA can defer review of a PD amendment

RFAs

- Limited to amendments seeking approval, with no new data or information (other than updated final labeling)
- Timeline:
  - RFA received 4-6 months before ELAD,* FDA will review and act on 90% of RFAs by the ELAD
  - RFA received <4 months but >30 days before the ELAD, FDA will strive to review the RFA by the ELAD
  - RFA received 30 or fewer days before the ELAD, FDA will strive to review within 30 days of receipt
  - RFA received more than 6 months prior to ELAD, FDA may request withdrawal and resubmission

*ELAD: Earliest Lawful Approval Date

PREA, IND, and BLA Transfer Improvements



PREA: FDA to develop a biosimilar-specific iPSP template (finalized NLT than August 31, 2028) and publish draft guidance on PREA compliance (NLT than December 31, 2028)



INDs: For multidose PK and/or PD studies in patients and comparative efficacy studies, FDA will strive to provide non-hold comments within 60 days of IND submission



BLA Transfers: FDA will strive to complete license revocation and reissuance for BLA transfer requests within 180 days of receipt of a complete submission

Excludes transfers with both CDER- and CBER-regulated BLAs and/or outstanding facility issues

Supplement Review Modernization

BsUFA III

4-Month
- New indications, PREA addressed
- CMC (SDRP and HF)

6-Month
- New indications, PREA not addressed
- Category D SDRP
- Labeling (HF)

10-Month
- Category F (Interchangeability, w/ or w/o HF study)
- Efficacy (SDRP and HF)

BsUFA IV

4-Month — **Category 1 Supplement**
- No new manufacturing, analytical, clinical, or human factors data
- Adding or modifying an indication; interchangeability

6-Month — **Category 2 Supplement**
- New manufacturing, analytical, clinical pharmacology, or human factors data
- New strengths, dosage forms, routes, or delivery devices/container closure systems (CCS)
- Any other supplement with HF data

- **Simplified structure:** BsUFA III six categories with clocks of 3, 4, 6, or 10 months become two BsUFA IV categories.
  - FDA to issue guidance/MAPP on BsUFA III Category A supplements
- **Category 1 (no new data):** indication changes and interchangeability (no HF data) get a single 4-month clock.
- **Category 2 (new data, strengths, forms, routes, or devices/CCS):** 6-month clock; no 10-month tier under BsUFA IV.

BsUFA IV: Final Combination Product & Human Factors Agreements

- **URRA/CA review goal.** FDA will provide agreement or non-agreement with comments for 90% of filed URRA or URRA/CA submissions within 60 days.

- **HF protocol review goal.** FDA will provide written comments for 90% of filed HF protocols (including CUHFS or alternative) within 60 days; submissions should include specific scientific or regulatory questions.

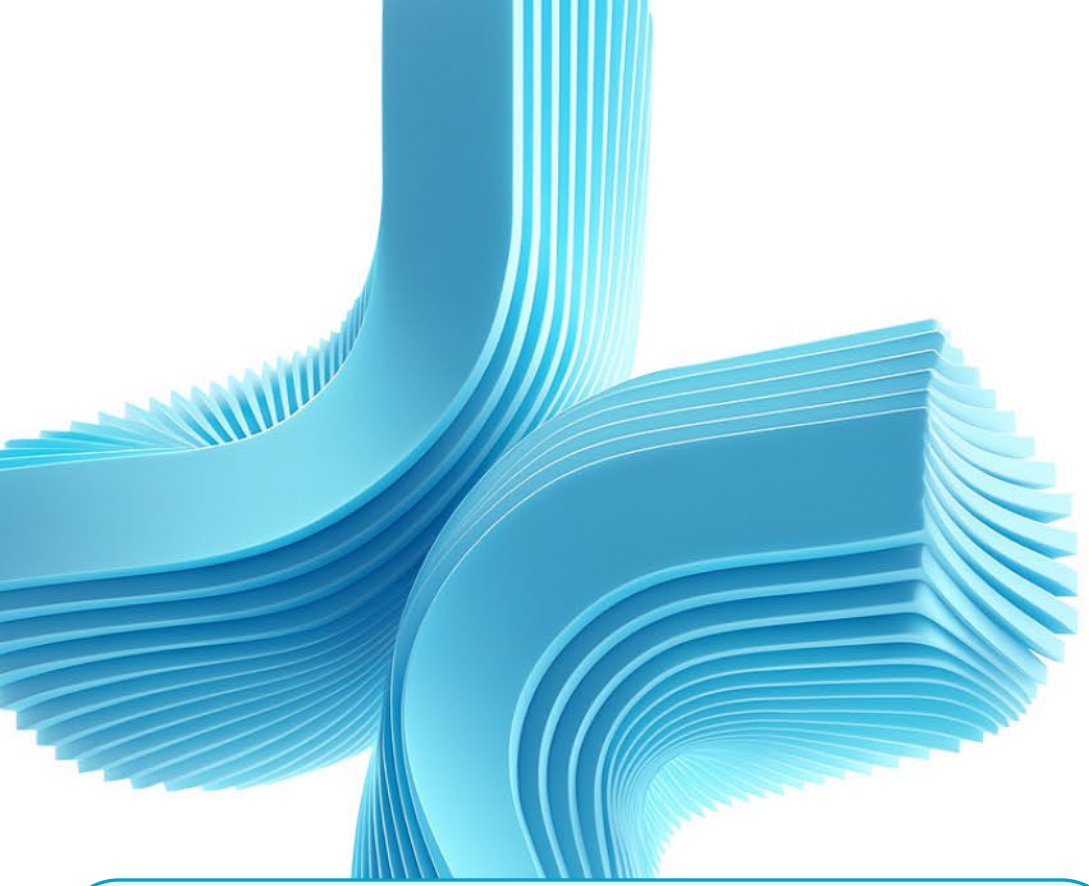
- **Submission pathways.** URRA/CA and HF protocols may be submitted to a pre-IND, IND, or BLA.

- **Type 2b dialogue option.** Sponsors may ask specific questions in a Type 2b package; the applicable timeline is then 90 calendar days.

- **Category 2 supplements.** Supplements containing new human factors data have a 6-month review goal.

- **Alternative-to-CUHFS guidance.** FDA will strive to issue draft guidance for interchangeable biosimilars by September 30, 2028, then work toward a revised draft or final guidance within 24 months after public comment closes.

The 60-day goal does not apply when the initial URRA/CA or HF protocol is submitted with, or to, a pending application or supplement.



How BsUFA IV Supports Biosimilar Combination Product Development

- **Earlier, decision-focused feedback.** Specific questions can be addressed before pivotal device and user-interface choices are locked.
- **Two engagement routes.** Sponsors can use the 60-day written-review pathway or choose a Type 2b meeting when dialogue is more valuable, accepting the 90-day meeting timeline.
- **Better sequencing discipline.** Because the 60-day goal does not apply to initial submissions made with or to a pending application or supplement, teams should complete URRA/CA and HF protocol alignment earlier.
- **Clearer study expectations.** FDA responses must explain disagreement with a URRA/CA justification or HF protocol design, supporting targeted revisions.
- **More predictable lifecycle planning.** New HF data are covered by the 6-month Category 2 supplement goal.
- **Potentially less burdensome evidence.** The planned guidance may identify scientifically appropriate alternatives to CUHFS for evaluating user-interface differences in interchangeable biosimilars.

Development takeaway
Submit URRA/CA and HF protocols before the marketing application, use focused questions and take advantage of Type 2b for issues requiring dialogue.

CMC Facility Lifecycle Management Program

A risk-based framework to address facility readiness earlier and reduce inspection-related complete response actions

1 PRE-SUBMISSION

CMC facility pre-submission meeting to discuss readiness, potential inspection or assessment issues, and expectations before original BLA submission

FDA guidance will describe readiness attributes, eligibility, meeting packages, and best practices.

2 DURING REVIEW / POST-PLI

When Form FDA 483 observations may affect approvability, FDA will inform the applicant and a focused post-PLI meeting may be requested.

Discussion centers on inspection findings and corrective actions that may be resolvable within the current review cycle. A single three-month goal-date extension may apply when new substantive information could support approval.

3 POST-ACTION

Following a facility-related CRL for an original BLA or CMC supplement, the applicant may request a BPD Type 1 post-action meeting.

The meeting is intended to clarify facility deficiencies and the corrective actions needed before approval or resubmission.

Program objective: earlier shared expectations, proactive facility readiness, more actionable inspection communication, and a greater opportunity for first-cycle approval.

Imminent Action & Missed Goal Date Accountability

BsUFA IV creates two distinct pathways when FDA cannot act by the original goal date

1 IMMINENT ACTION: LIMITED FLEXIBILITY

FDA may continue review for up to 60 days beyond the goal date when approval or a provisional determination is expected.

Permitted circumstances include late-cycle reference product labeling or REMS changes, expiration of blocking exclusivity, late unsolicited amendments, and one or more “small issues” for original BLAs.

FDA must notify the applicant, identify the basis, describe remaining issues, and provide a target action date.

2 MISSED GOAL DATE: TRANSPARENCY & ACCOUNTABILITY

If imminent action is not invoked, FDA will notify the applicant by the goal date that the BLA or supplement goal will be missed.

FDA will identify the cause of delay, issue unrelated outstanding IRs, and assign a target action date six months after the original goal date while striving to act sooner.

If the target date is missed, FDA will provide a further status update and, when feasible, an estimated timeline for action.

Practical impact: fewer avoidable CRLs, clearer escalation points, and improved launch planning when review extends beyond the original clock.

Additional Slides

Where BsUFA IV Stands: Reauthorization Process

Date	Milestone
Dec. 3, 2025	FDA public meeting to kick off reauthorization; stakeholder input
Apr. 7 – June 30, 2026	FDA–industry negotiations and monthly patient/consumer consultations; minutes posted
Sept. 25, 2026	Proposed recommendations published in the Federal Register (91 FR 60962)
Oct. 16, 2026	Deadline to register to make an oral comment at the public meeting
Oct. 26, 2026	Hybrid public meeting, FDA White Oak and Microsoft Teams, 9:00 AM – 12:00 PM ET
Nov. 25, 2026	Written comments due, Docket FDA-2015-N-3326 (11:59 PM ET); late comments will not be considered
Jan. 15, 2027	Statutory deadline for FDA to transmit final BsUFA IV recommendations to Congress
Sept. 30, 2027	BsUFA III authority expires; without legislation, no FY2028 fees
Oct. 1, 2027	BsUFA IV (FY2028–2032) takes effect, if enacted

Status: The commitment letter is proposed, not final. Fee changes require legislation, and annual fee rates are set by separate Federal Register notice.

Sources: FR notice, Docket FDA-2015-N-3326 (Sept. 25, 2026); FD&C Act § 744I(f)