# Biosimilar User Fee Act (BsUFA) Reauthorization

### FDA and Industry Negotiation Meeting

May 12, 2026 | 9:30 am–3:00 pm

Virtual Format

## MEETING PURPOSE

To discuss Industry's inter-center consultative review (ICCR), modernizing biologics license application (BLA) review, and exclusivity determinations proposals, and FDA's data fidelity proposal.

## PARTICIPANTS

| FDA | | INDUSTRY | |
|---|---|---|---|
| Sonday Kelly | CBER | Giuseppe Randazzo | AAM |
| Katie Rivers | CBER | Scott Kuzner | AAM |
| Andrew Kish | CDER | Jessica Greenbaum | AAM (Sandoz) |
| Ashley Boam | CDER | Cory Wohlbach | AAM (Teva Pharmaceuticals) |
| Emanuela Lacana | CDER | Derek Scholes | BIO |
| Irene Chan | CDER | Lina AlJuburi | BIO (Sanofi) |
| Joel Welch | CDER | Bee Reed | Biosimilars Forum |
| Joshua Barton | CDER | Hillel Cohen | Biosimilars Forum |
| Kimberly Taylor | CDER | Juliana Reed | Biosimilars Forum |
| Kristopher Hoover | CDER | Andrew Zacher | Biosimilars Forum (Amneal) |
| Larry Lee | CDER | Scott Tomsky | Biosimilars Forum (Biocon Biologics) |
| Laurel Goldberg | CDER | Kristy Lupejkis | PhRMA |
| Mustafa Unlu | CDER | Ryan Kaat | PhRMA |
| Nikolay Nikolov | CDER | Sean Hilscher | PhRMA |
| Nina Brahme | CDER | Leah Christl | PhRMA (Amgen) |
| Paul Phillips | CDER | | |
| Sarah Ikenberry | CDER | | |
| Sarah Yim | CDER | | |
| Stacey Ricci | CDER | | |
| Thamar Bailey | CDER | | |
| Joshua Ostrer | OCC | | |
| Marianne Terrot | OCC | | |

## MEETING SUMMARY

FDA summarized the first stakeholder consultation meeting, which was held on April 27th. Following the summary, FDA presented a revised data fidelity proposal and counterproposals to Industry's Modernizing BLA Review subproposals. FDA and Industry agreed to discontinue discussions on one Modernizing BLA Review subproposal, which aimed to establish a 10-month review clock for certain 351(k) BLAs. Industry responded to FDA's exclusivity determinations counterproposal. FDA then followed up on the status of Industry's ICCR proposal and presented the status of ongoing negotiations.

### Stakeholder Meeting Summary

FDA presented a summary of the first BsUFA stakeholder consultation meeting, noting that for every month that FDA conducts negotiations meetings with Industry, FDA also holds a stakeholder consultation meeting with patient and consumer groups that registered to participate. FDA said that the initial stakeholder consultation meeting, held on April 27th, focused on explaining the BsUFA reauthorization process, clarifying the scope of BsUFA negotiations, and collecting initial perspectives from the participants. FDA shared that stakeholder participants expressed support for the BsUFA program and identified interchangeability as a top priority for future discussion, with particular interest in patient education. FDA noted that stakeholder participants raised concerns about the Agency's staffing capacity to manage the anticipated increase in biosimilar applications as major biologic patents expire and requested greater transparency regarding staffing and financial resources as they pertain to the biosimilar program.

Industry acknowledged the importance of stakeholder participation and requested the Agency communicate if additional stakeholder education on the BsUFA program would be helpful.

### FDA Data Fidelity Proposal

During the April 21st meeting, FDA presented a data fidelity proposal, which aimed to extend the goal date for 6 months when a data fidelity issue is identified to allow time to understand the extent of the issue and any impact on the application prior to the goal date. As part of the proposal presentation, FDA acknowledged that data fidelity issues in the biosimilar program are rare and not a biosimilar-specific issue but noted their proposal would provide more visibility and transparency for applicants if a data fidelity issue were to occur.

During the May 12th meeting, FDA acknowledged Industry's previous concern regarding the potential for a misunderstanding of the prevalence of data fidelity issues in the biosimilar program if this proposal were to move forward. To address this concern, FDA proposed replacing the "data fidelity" terminology with "complex data issue." FDA also proposed shortening the goal extension duration from 6 months to 3 months, acknowledging the rare occurrence of data fidelity issues in the biosimilar program. FDA would also exclude these applications from

performance goal metrics. FDA said the Agency continues to see value in this proposal and noted the potential for a possible multiplier effect in the future, where a data fidelity issue at one facility has the potential to impact multiple applications, particularly as the biosimilar program continues to grow in size.

Industry shared appreciation for the proposed change in terminology but noted that, given the shared understanding that data fidelity is not a biosimilar-specific issue, they remain not fully aligned on the problem statement the proposal aims to address. During the April 21st meeting, Industry noted that this proposal was not included in all of the recent user fee negotiations, including the Prescription Drug User Fee Act (PDUFA).

Industry and FDA agreed to temporarily pause discussion on the data fidelity proposal while the group continues to negotiate FDA's inspections-related proposal, which Industry said they believe may address some of the issues FDA identified in the data fidelity proposal problem statement.

### FDA Modernizing Biologics License Application (BLA) Review Counterproposals

During the April 28th meeting, Industry presented several Modernizing BLA Review subproposals, including proposals regarding reassigning missed goal dates, BLA transfer requests, approved BLA transparency, and review clock timelines. During the May 12th meeting, FDA presented responses to each of these subproposals.

Regarding Industry's proposal to establish a process to assign a new goal date after the original goal date was missed, FDA agreed to apply a second goal date but proposed applicability exceptions. FDA said that if the Agency's imminent action, data fidelity, and/or facility lifecycle proposals were to be adopted in BsUFA IV, then a second goal date would not be applied in circumstances where these other extended timeline provisions are applied. In addition, FDA said the Agency does not agree to establish a performance goal but is willing to annually report the number of second goal dates assigned and the number of second goal dates that were met.

Industry asked clarifying questions regarding instances when a second goal date would be applied. Industry also inquired whether FDA was willing to agree to communicate any outstanding application issues as of the goal date. Industry explained that the communication and transparency element is a key aspect of their proposal, because applicants could continue to work on outstanding issues as the application is pending. FDA said the Agency's current practice is to communicate with applicants as needed to address application issues. Following a caucus, Industry said they would provide additional detail on the communication aspects of their original proposal in a future meeting.

In response to Industry's proposal to establish a timeline for completing BLA transfer requests, FDA presented data on BLA transfer request timelines and proposed an 180-day timeline to complete transfer requests. FDA said the 180-day timeline would not be applicable to instances where transfers include (1) applicants that span multiple centers and (2) applications with

outstanding facility issues. FDA said the 180-day timeline would begin when the Agency receives a complete transfer request, noting that all of the necessary information must be provided by the applicant before the clock starts. In addition, FDA said they were willing to annually report the number of transfers and corresponding time to completion. FDA confirmed this proposal is resource neutral and noted that the proposed timeline would only apply to 351(k) transfer requests.

Industry requested clarity on the methodology that informed the 180-day timeline counter proposal and whether the FDA would communicate when the 180-day timeline begins. FDA shared the proposed timeline was informed by the presented transfer timelines data and limited staffing assigned to transfer processing and affirmed the Agency would communicate the timeline initiation. Following a caucus, Industry said they were conceptually aligned with FDA's counterproposal and would follow up in a future meeting.

Regarding Industry's proposal for approved BLA transparency, FDA said the Agency was willing to commit to (1) publishing redacted 351(k) BLA action packages 60 days following licensure, (2) providing regulatory reviews to applicants within 40 days of publishing the action package, and (3) establishing a performance goal. FDA said their counterproposal would require resources.

Industry requested the Agency consider a resource estimate to facilitate the redaction of 351(a) supplements, noting that action packages for reference products help advance biosimilar development, including when a biosimilar applicant provides a certain rationale or justifications that are tied to findings for the 351(a) BLA reference product. FDA said they would follow up on this proposal in a future meeting.

FDA also followed up on the status of Industry's proposal to shorten the 351(k) BLA review clock to 10 months for submissions that do not contain clinical efficacy studies. During the April 28th meeting, FDA stated that the shift away from efficacy studies does not translate to a shortened review process because reviews are done in parallel, not sequentially. Additionally, FDA explained that potential time saving from leveraging artificial intelligence-based tools (*e.g.*, during the filing review) could not yet be accounted for in review timelines. In turn, the Agency said they don't see a path forward for this proposal in negotiations. FDA and Industry agreed to discontinue discussion on this proposal.

### Industry Exclusivity Determinations Proposal

During the May 5th meeting, FDA presented an exclusivity determination counterproposal, noting that the Agency was willing to commit to publishing a limited number of reference product exclusivity (RPE) determinations each year, with the reference products being selected at FDA's discretion, and opening a public docket to solicit stakeholder input on which determinations would be most useful. FDA noted that anonymous public docket submissions or attorney-mediated submissions could alleviate disclosure concerns.

During the May 12th meeting, Industry responded to FDA's counterproposal, noting the proposal does not address their challenges. Industry said RPE is a critical component for pipeline planning and long-term portfolio management and that the regulatory uncertainty surrounding RPE can deter and delay development. Industry communicated that the limited number of RPE determinations FDA proposed is not sufficient. Industry also raised concerns about RPE determinations being at the Agency's discretion, especially given that FDA noted it would primarily focus on RPE determinations only to products for which the application of the statute was relatively straightforward. In turn, Industry inquired whether the Agency would be willing to consider an alternative approach under which a prospective biosimilar applicant could formally request an RPE determination and the Agency would have an established timeline to make the determination.

FDA inquired whether the request-based approach would have any limitations or guardrails on the total number of RPE determination requests, who could request RPE determinations, and how many requests could come in at one time. FDA noted that without limitations the Agency could be inundanted with requests, which would be challenging to address even with additional resources. FDA said establishing a realistic process for such an approach is challenging and noted that it would be difficult to envision a process as structured as a scientific review process to address RPE determinations, which involve complex legal and policy matters.

Industry voiced concerns regarding FDA's inquiry into whether there would be a "cap" on the number of requests industry could submit per year. Industry responded that there could not be a cap on the number of requests per year, as that would not solve the problem Industry is facing. Industry also clarified that FDA would be expected to substantively assess RPE upon receipt of a request—*i.e.*, FDA could not defer making a decision.

FDA acknowledged Industry' position, while noting that determining RPE remains a challenging policy issue and, in the Agency's view, may not be addressable in the Commitment Letter. Industry explained that this important issue needs a solution and said they would provide more details on their counterproposal in a future meeting.

### Industry Inter-center Consultative Review (ICCR) Proposal

FDA followed up on the status of Industry's ICCR proposal, which aimed to ensure all Agency centers and divisions consulted for ICCRs are subject to the same BsUFA timelines outlined in the commitment letter. During the April 23rd meeting, FDA stated that all centers and divisions consulted for ICCRs are already subject to BsUFA timelines. During the May 12th meeting, Industry clarified that their proposal aims to include language in the commitment letter confirming all of the relevant parties are held to the same timeline. Industry also said they were open to having ICCRs evaluated as part of the third-party assessment FDA proposed during the May 7th meeting.

Following a caucus, FDA said that neither the Prescription Drug User Fee Act (PDUFA) nor the BsUFA commitment letter includes specific language that states centers or divisions are bound by UFA timelines, noting timeline adherence is implied. FDA said the Agency is not willing to include specified language.

FDA and Industry agreed to include ICCR as a topic in the third-party assessment.

### BsUFA IV Negotiations Progress Check

FDA presented the status of all of the ongoing proposals that were initially presented during the April 7th meeting. FDA and Industry reaffirmed their (1) agreement to discontinue discussion of the Modernizing BLA Review subproposal, which aimed to establish a 10-month review clock for 351(k) BLAs that do not contain clinical efficacy studies, and (2) conceptual alignment on FDA's Modernizing BLA Review counterproposal regarding BLA transfer requests.

### Next Steps

The goal for the next meeting on May 14th is to discuss draft language for FDA's proposal on regulatory science, FDA's proposal on imminent action, FDA's response to Industry's Modernizing BLA review proposal, and FDA's response to Industry questions about FDA's meetings proposal.