# Biosimilar User Fee Act (BsUFA) Reauthorization

### FDA and Industry Negotiation Meeting

April 28, 2026 | 9:30 am – 3:00 pm

Virtual Format

## MEETING PURPOSE

To discuss Industry's modernizing BLA review, enhancing review efficiency, and regulatory science proposals, and FDA's regulatory science proposal.

## PARTICIPANTS

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

## MEETING SUMMARY

FDA and Industry presented their respective regulatory science proposals and exchanged clarifying questions. Industry then presented their "Enhance Review Efficiency" subproposal

and FDA asked clarifying questions. Then, Industry presented their "Modernize BLA Review" subproposals and FDA asked clarifying questions.

### Regulatory Science Proposals

FDA presented the details of their regulatory science proposal, noting that the two regulatory objectives of the BsUFA III Regulatory Science Pilot Program, increasing reliance on analytical data and reducing the use of human subjects, have been met. FDA said that the Agency has shifted its priorities to predominately focus on the efficiency of core review work. In turn, the Agency proposed ending the regulatory science pilot program. FDA said that if the pilot program were to end, supportive staffing resources could potentially be reallocated and, to the extent possible, the results of ongoing research projects would still be summarized and shared publicly.

Industry presented the details of their regulatory science proposal, noting that they believe the current biosimilar regulatory science framework could benefit from increased transparency and accountability and is not set up to address the next generation of biosimilars. In turn, and to help ensure that research projects align with program goals and provide meaningful value to biosimilar development, Industry proposed increasing their involvement in establishing research priorities, requiring the FDA to commit to annual stakeholder engagement meetings to review research progress and routine publication of research outcomes, and establishing a research selection process that includes the solicitation of stakeholder input.

FDA stated, from its perspective, that Industry's proposal aligns with how the current pilot program already operates. FDA said the Agency solicited Industry input during the pilot program, but Industry did not provide much feedback. FDA also acknowledged that one of Industry's finance proposals seeks to limit the mechanism currently used to fund the pilot.

In the absence of a formal regulatory science program and in the event future research is conducted utilizing BsUFA funds, Industry requested that a process be established to ensure they can provide feedback on research topics and provide additional transparency, if/when they arise. FDA said they would follow up on this proposal in a future meeting.

### Industry Late Cycle Meeting (LCM) Proposal

During the April 7th meeting, Industry introduced a proposal titled "Enhance Review Efficiency," which comprises several subproposals including a Late Cycle Meeting (LCM) proposal. During the April 28th meeting, Industry noted that the BsUFA III commitment letter states that FDA intends to complete primary and secondary reviews by the LCM. Industry also presented the details of their LCM proposal, noting that substantive review issues are sometimes communicated after LCMs, which does not allow time for sponsors to respond effectively, as intended. In turn, Industry proposed that the FDA commit to notifying sponsors whether primary and secondary reviews are complete and, if not, provide a plan for meeting the action

date by the LCM or 60 days prior to the goal date (whichever is earlier), highlighting that under the current BsUFA III commitment FDA already intends to complete such reviews in advance of the LCM. Industry said their proposal aims to improve predictability and transparency for applicants, who would likely anticipate information requests (IRs) if the primary and secondary reviews were not completed by the LCM. Industry said their proposal is for the FDA to better communicate the status of the review.

FDA said they are sympathetic to Industry's need for transparency; however, the Agency does not believe this proposal will achieve the stated aim. FDA said that in most cases the primary and secondary reviews are complete by the LCM, but the Agency is waiting to finalize the review because they may need to resolve elements later in the review cycle. FDA and Industry discussed what each group means when they refer to a "complete" review. For example, FDA said the Agency may be waiting on inspections or changes in the reference product that may impact the biosimilar. Industry explained FDA's current practice of communicating "no issues identified" during the LCM does not address the critical question of whether that is because FDA has not completed its substantive review (and so the applicant should be prepared for additional IRs) or whether because there are no open issues at that time. FDA said they would provide a response to this proposal in a future meeting.

### Industry Modernize BLA Review Subproposals

During the April 7th meeting, Industry introduced a proposal titled "Modernize BLA Review," which comprises several subproposals regarding review clock timelines, reassigning missed goal dates, major amendments, BLA transfer requests, transparency for approved BLAs , and information requests (IRs). Industry's subproposals include several changes that aim to improve efficiency and transparency.

Industry proposed shortening the 351(k) BLA review clock to 10 months for submissions that do not contain clinical efficacy studies and moving the mid cycle and late cycle meetings accordingly. Industry said using technology to do some of the administrative work could eliminate the 2-month filing period. In response, 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. FDA said product quality and manufacturing are the bulk of the submission review, and shortening the review clock would be asking reviewers to move faster without adequate resources. FDA said while potential efficiency gains related to artificial intelligence pilot projects are promising, it is difficult for FDA to commit to changes until the gains have been fully operationalized and realized in the program. For the reasons stated above, FDA said they do not see a path forward for this proposal in negotiations.

Industry then proposed establishing a process to assign a new goal date after the original goal date was missed and provide for additional communication touchpoints. Industry said their proposal would offer more structure and transparency for sponsors, noting that when a goal date

is missed there is no clear process forward. In response, while FDA noted that some of their other proposals address Industry's underlying concern, FDA acknowledged that there might be policy or legal considerations that could result in a missed goal date, which are issues that would not be addressed by the Agency's other proposals.

Next, Industry proposed that FDA commit to establishing criteria to distinguish between major amendments and other amendments, providing a rationale to sponsors when the Agency makes a major amendment classification, establishing a process for sponsors to request the Agency to reconsider a major amendment classification, and publicly reporting clock extensions. Industry said their proposal would provide predictability and transparency for sponsors as they plan for product launch. Industry also said there were instances when FDA classified amendments as major even though, from Industry's perspective, the amendment did not include the type of data for a major amendment. In response, FDA said it is current practice for Agency to notify sponsors of the basis of a major amendment issuance. FDA noted, and Industry acknowledged, that major amendments are a rare event in the biosimilar program. FDA said in many instances the Agency will issue a major amendment to address issues and ultimately get to an approval on the first review cycle rather than issuing a complete response letter.

Industry then proposed establishing a timeline for completing BLA transfer requests, noting that currently there is no established timeline for this process. In response, FDA stated that there is currently one person that manages BLA transfer requests sent to the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER). FDA said the same person is responsible for other duties, including updates to the Purple Book. FDA said they would consider Industry's proposal but noted it will likely require hiring additional resources.

In addition, Industry proposed the FDA commit to providing redacted regulatory reviews to applicants upon approval, publishing redacted 351(k) BLA action packages within a specified period, and establishing a process to publish redacted 351(a) BLAs. Industry said access to regulatory reviews enables applicants to better understand regulatory expectations. In response, FDA requested clarity on whether Industry is requesting redacted complete response letters in connection with the proposal for the applicant to receive redacted copies of regulatory reviews for its BLA and whether Industry is requesting posting of redacted action packages for supplements in addition to BLA approvals. FDA raised concerns about negotiating redacted 351(a) BLAs given those applications are covered by Prescription Drug User Fee Act (PDUFA) and the current negotiations are limited to BsUFA applications and processes. FDA stated that committing to additional redaction work would require hiring additional resources, noting they would provide a resource estimate in a future meeting.

Industry stated, and FDA acknowledged, that they no longer plan to bring forward a proposal on the IR process. FDA said they would follow up on Industry's remaining subproposals in a future meeting.

**Next Steps**

The goal for the next meeting on April 30th is to continue discussing FDA's supplements proposal, Industry's combination products proposal, and Industry's and FDA's respective meetings proposals.