



Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Negotiation Meeting

April 21, 2026 | 9:30 am – 3:00 pm

Virtual Format

MEETING PURPOSE

To discuss FDA’s data fidelity, provisional determinations, and imminent action proposals, and Industry’s exclusivity determinations proposal, labeling proposal, Risk Evaluation and Mitigation Strategies (REMS) proposal, and response to FDA’s Pediatric Research Equity Act (PREA) counterproposal.

PARTICIPANTS

FDA

Sunday Kelly	CBER
Andrew Kish	CDER
Ashley Boam	CDER
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Irene Chan	CDER
Joel Welch	CDER
Kimberly Taylor	CDER
Kristopher Hoover	CDER
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Laurel Goldberg	CDER
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Paul Phillips	CDER
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INDUSTRY

Alisha Sud	AAM
Giuseppe Randazzo	AAM
Scott Kuzner	AAM
Jessica Greenbaum	AAM (Sandoz)
Cory Wohlbach	AAM (Teva Pharmaceuticals)
Derek Scholes	BIO
Lina AlJuburi	BIO (Sanofi)
Bee Reed	Biosimilars Forum
Hillel Cohen	Biosimilars Forum
Juliana Reed	Biosimilars Forum
Andrew Zacher	Biosimilars Forum (Amneal)
Scott Tomsky	Biosimilars Forum (Biocon Biologics)
Ryan Kaat	PhRMA
Sean Hilscher	PhRMA
Leah Christl	PhRMA (Amgen)

MEETING SUMMARY

Industry asked clarifying questions regarding FDA's PREA counterproposal. FDA responded to Industry's questions. FDA then presented their data fidelity and provisional determinations proposals. Industry asked clarifying questions following each proposal presentation. Next, Industry presented their exclusivity determinations proposal and FDA asked clarifying questions. FDA presented their imminent action proposal and Industry asked clarifying questions. Industry then presented their labeling and REMS proposals, and FDA asked clarifying questions.

Industry Response to FDA Pediatric Research Equity Act (PREA) counterproposal

In response to FDA's PREA counterproposal, Industry requested clarity on whether FDA's proposal is for the Agency to publish a draft initial pediatric study plan (iPSP) template for Industry to provide comments on, or whether the proposal intends to solicit comments to inform the creation of a draft template. Industry also reiterated their previous position that they believe a streamlined template would bring efficiencies, but they do not believe the streamlined template will completely address Agency delays in meeting iPSP review timelines. Industry inquired whether the Agency would be willing to commit to process-related changes to address this pain point. Industry also requested clarity on how the Agency proposed to refer to the publication of a pediatric study plan guidance for biosimilar products in the commitment letter.

FDA reiterated that their counterproposal is to publish a biosimilar-specific iPSP template in the Federal Register and establish a docket for public comment. FDA stated their position that the streamlined template would address the burden of extraneous content in iPSPs. FDA requested Industry provide data supporting their position that there are systematic iPSP review delays. Regarding the commitment letter reference to the guidance, FDA proposed modeling the reference on the language used in prior Generic Drug User Fee Act (GDUFA) commitment letters. Industry and FDA agreed to share data on historical iPSP review timelines in a future meeting.

FDA Data Fidelity Proposal

FDA presented the details of their data fidelity proposal, noting that a single data fidelity issue can impact multiple applications and the outcome of how the issue is addressed is a lengthy and variable process, which can result in missed goal dates. FDA acknowledged that data fidelity issues can occur in any application and are not a biosimilar-specific issue. FDA acknowledged that data fidelity issues in the biosimilar program are rare. FDA said analytical data is complex and is often split across many testing locations, which enhances potential data fidelity issues to work through. In turn, FDA proposed extending 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. FDA said under this proposal, the Agency would only be able to extend the goal date once. If the issue is not resolved by the newly assigned goal date, the Agency

said they would notify the applicant and contact the relevant site or facility and offer a meeting. FDA acknowledged that their proposed goal extension provision would rarely be used but, when used, it would provide more visibility and transparency for applicants.

Industry asked why this proposal was not included in all of the recent user fee negotiations, including the Prescription Drug User Fee Act (PDUFA) negotiations, since data fidelity issues are not specific to biosimilars. Industry asked why this proposal is necessary given the low occurrence rate of data fidelity issues in the biosimilar program. Industry also raised concerns regarding the potential for misinformation in the public domain regarding biosimilars given this proposal does not address a biosimilar-specific issue and the occurrence of the issue in biosimilars is rare. Industry also requested clarity on how the Agency would communicate with sponsors if a data fidelity issue occurred.

FDA agreed that this issue was not unique to biosimilars. FDA stated that the proposed 6-month goal extension provision would allow the Agency to notify applicants of facility data fidelity issues early, providing predictability around review timelines, and that sponsors would be informed of any such issues prior to their application goal date.

FDA said they would follow up on this proposal in a future meeting.

FDA Provisional Determinations (PDs) Proposal

FDA presented the details of their PDs proposal, noting that this proposal aims to establish timelines to approve applications that were previously blocked from approval by exclusivity. FDA said that 351(k) applications are placed in a PD status if they meet the licensure standard but cannot be approved because of unexpired exclusivity. FDA said that the absence of established timelines for approving applications with a PD status once exclusivity expires creates uncertainty for both applicants and the Agency around submission and review timing. FDA proposed establishing a formalized timeline with clear submission deadlines that facilitate reviews ahead of exclusivity expiration. FDA proposed a performance goal for approval requests submitted within a specified time period prior to exclusivity expiration, which would be the goal date. FDA said their proposal accounts for the various exclusivity types, which are complicated and require different factual and timing scenarios. FDA said this proposal would require resources.

Industry requested clarity on how they would be able to submit approval requests within the proposed window if the FDA has not posted the relevant expiry date(s) for reference product exclusivity (RPE) or first interchangeable exclusivity (FIE). Industry also requested clarity on how the FDA would address supplements or amendments submitted while a 351(k) application has a PD status and what kind of supplements could be submitted during the proposed window prior to exclusivity expiration.

FDA acknowledged that it may sometimes be challenging to determine when exclusivity will expire since FDA will not have the relevant information or may be working through the complex and novel issues that exclusivity can raise; however, in the instances that exclusivity is known,

the proposed review timelines would apply. FDA said they would provide a response on Industry's remaining questions during a future meeting.

Industry Exclusivity Determinations Proposal

Industry presented the details of their exclusivity determinations proposal, stating that since the passage of the BPCIA in 2009, the FDA is required to update the Purple Book with RPE expiry dates, which currently contains only four RPE determinations. Industry said FDA routinely makes exclusivity determinations at the time of approval for drugs approved under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act. Industry explained that knowing when a RPE is set to expire is critical to pipeline selection and development timelines, and that as such, this information is important before full biosimilar development is undertaken. Industry proposed establishing goal dates for RPE determinations within a designated period following licensure of any biological product under section 351(a). Industry also proposed the FDA commit to a phased goal to evaluate RPE eligibility for all of the currently approved 351(a) biologics by the end of BsUFA IV.

FDA acknowledged Industry's need for clarity around RPE determinations but noted that the 505(c) comparison is not relevant. FDA noted that exclusivity questions under the Hatch-Waxman Act have a much longer history, an established system, and more resources compared to biosimilar-specific exclusivities. FDA said the Agency is extremely limited in the number of resources available to make RPE determinations. FDA also said that they have prioritized their limited resources and efforts on FIE-related matters due to regulatory necessity. FDA said making RPE determinations is resource-intensive and requires the Agency to work through foundational questions on how to interpret the BPCI Act, some of which remain unsolved. FDA also noted that Industry should be aware of the vast majority of RPE expiry dates, given that most reference products are subject to a 12-year exclusivity period.

Industry acknowledged the challenges associated with making RPE determinations and requested the agency to consider alternatives to address their stated goal of publishing RPE determinations.

FDA and Industry agreed to consider approaches to identify and prioritize RPE determination for products where exclusivity is uncertain and follow up on this proposal in a future meeting.

FDA Imminent Action (IA) Proposal

FDA presented the details of their IA proposal, noting that circumstances outside of an applicant's control can at times create challenges for review teams and applicants to meet goal dates. For example, FDA said reference product labeling changes that occur late in the 351(k) review process can require a tremendous amount of work in a short time, which is not sustainable. In turn, the FDA proposed establishing an IA process, which would allow the Agency to work up to 60 days past the goal date to support approval when certain late-stage issues arise

that the agency believes are resolvable within those 60 days. FDA proposed four categories of issues where the IA process could apply: (1) reference product labeling changes, (2) REMS-related issues/changes, (3) blocking exclusivity, and (4) resolution of small issues including an FDA request for an amendment that does not include new data sets. FDA said this proposal would apply to both original 351(k) applications and supplements, and that the FDA would notify applicants by the goal date when IA is invoked. FDA said their proposal is similar to the IA process under the GDUFA program.

Industry requested additional clarity on what would trigger the IA process, including a definition of what was termed “small issues.” Industry also requested clarity on how the Agency envisioned communicating with sponsors when the IA process has been triggered. Industry requested the FDA to consider how imminent action would apply when there competing applications (e.g., multiple applications under review when FIE is at play).

FDA stated that the Agency does not intend to use the IA process frequently, but rather only in a narrow set of circumstances that cause challenges in completing a review by the goal date when imminent approval may be possible. FDA said that it was not possible to provide a definitive and comprehensive explanation of “small issues,” but instead provided several examples, including last-minute changes to withdraw a strength, add a new indication, or seek interchangeability. Regarding communication, the Agency said regulatory project managers (RPMs) would notify Industry by the goal date that the IA process had been invoked and provide additional high-level details, if possible, to explain the reason. With respect to FIE, FDA said they would provide a response in a future meeting.

Industry Labeling Proposal

Industry presented the details of their labeling proposal, noting that when FDA labeling comments are provided late in the review cycle the opportunity for meaningful dialogue with the Agency is limited. In turn, Industry proposed FDA commit to a performance goal to provide the first set of complete labeling commitments no later than the mid-cycle meeting.

FDA said that Industry's proposal does not account for circumstances outside of the Agency's control, such as reference product labeling changes, and that existing processes already serve to streamline labeling review when reference product labeling changes occur late in 351(k) BLA review. The agency said Industry's proposal would require all of the relevant disciplines to be done reviewing their portion of the BLA at mid-cycle. FDA requested clarity on whether (1) “complete” labeling comments refers to feedback from all of the relevant disciplines and (2) Industry considered that receiving labeling comments earlier in the process may result in multiple rounds of feedback than if provided later in the process.

Industry said their proposal aims to finish labeling discussions with the Agency as early in the process as possible, acknowledging that there still might be late-breaking changes to reference product labeling that occur late in the review cycle. Industry acknowledged that the mid-cycle

point may not be the right time for the Agency to provide a complete set of labeling comments and asked the Agency to consider when might be the right time to start labeling discussions so there is not a scramble to address labeling late in the review process. Industry clarified that a “complete” set of labeling comments would include comments from all of the relevant disciplines and address the instructions for use (IFU), the carton, and the package.

FDA said they would provide a response to this proposal in a future meeting

Industry Risk Evaluation and Mitigation Strategies (REMS) Proposal

During the April 7th meeting, Industry introduced a proposal titled “Enhance Review Efficiency,” which comprises several subproposals including a REMS proposal. During the April 21st meeting, Industry presented the details of their REMS proposal, noting that when FDA feedback on REMS is delayed it can create uncertainty late in the review cycle and impact the timing of application approval, which can delay product launch. In turn, Industry proposed that FDA establish a review timeframe for FDA and Industry to reach agreement on REMS packages two months prior to 351(k) application goal dates.

FDA noted that REMS are closely tied to labeling. As a result, FDA said REMS materials may need to be adjusted based on the result of FDA and Industry labeling discussions. FDA also noted that, unlike in the Prescription Drug User Fee Act (PDUFA) program, the biosimilar program does not statutorily require shared systems, so many sponsors are developing individual REMS programs that require review. FDA said that Industry’s proposal raises feasibility concerns, noting that moving up the labeling and REMS discussions would effectively shorten timelines for reviewers.

Industry acknowledged the link between REMS and labeling, noting that they are looking for optimal communication timing and getting to the point where all of the REMs and labeling discussions are smoothed out in advance of the goal date. Industry also acknowledged the Agency’s feasibility concerns and noted they would be open to alternatives to facilitate more predictability around REMs review timelines.

FDA said an alternative to Industry’s proposal could be to conduct a third-party assessment to identify possible process enhancements. FDA said they would follow up on this proposal in a future meeting.

Next Steps

The goal for the next meeting on April 23rd is to discuss FDA’s response to Industry’s proposals on combination products, Inter-Center Consultative Review (ICCR), Investigational New Drug (IND) protocols.