Summary of views and comments received regarding proposed recommendations for BsUFA III
Docket No. 2015-N-3326

Introduction and Background

The Biosimilar User Fee Act (BsUFA) authorizes the Food and Drug Administration (FDA or Agency) to collect user fees to support the process for the review of biosimilar biological product applications. The current legislative authority for BsUFA expires on October 1, 2022. To develop recommendations for the third reauthorization of BsUFA (BsUFA III), FDA has followed the process described by statute, including two public meetings with associated dockets for public comment and negotiations with the regulated industry.

FDA began the reauthorization process, in preparation for BsUFA III, with a public meeting held on November 19, 2020. Following the meeting, a docket was open for 30 days for the public to submit written comments. In March 2021, FDA began negotiations with regulated industry to determine the proposed recommendations for the next BsUFA program. These discussions concluded in June 2021. Minutes of these meetings are posted on FDA's website at https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iii-fiscal-years-2023-2027.

The statute further requires FDA to publish the recommendations in the Federal Register and hold a public meeting at which the public may present its views. This public meeting was held on November 2, 2021. The associated public docket was available for comment from September 22 to December 2, 2021. The FDA must then consider the public views and comments and revise such recommendations as necessary. When transmitting the recommendations to the Congress, the Secretary must provide a summary of the public views and comments and any changes made to the recommendations in response to the views and comments. This document fulfills that requirement.

Overview of Public Comments

FDA received five public comments in response to the public docket. These comments were from professional and trade associations, and an individual member of the public. Overall, the comments reflect general support for the recommendations for reauthorization. A few comments included considerations for implementation of the recommendations.

Broad support for the proposed recommendations

The commenters emphasized the importance of BsUFA in facilitating the development of safe and effective biosimilar products for the American public, with the potential to offer life-saving or life-altering benefits at reduced cost to patients. Commenters highlighted that the BsUFA III recommendations will continue to mature the biosimilar review program and make improvements to advance biosimilar product development.

Commenters expressed support for the introduction of new supplement categories and review timelines in BsUFA III to improve the efficiency of the review process. Commenters also praised the changes to meeting management goals, particularly the modification to the Biosimilar Initial Advisory meeting, and the introduction of the new Type 2a meeting type for rapid, targeted feedback, and follow-up opportunities after a meeting or written response only to clarify FDA's feedback.

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Commenters offered support for the regulatory science pilot program and the activities to advance development of interchangeable products in BsUFA III. Several commenters noted the importance of the regulatory science program in advancing efficient biosimilar development, enhancing regulatory clarity, and providing a forum for stakeholder engagement. One commenter encouraged FDA to complete the regulatory science pilot program deliverables as soon as possible in BsUFA III. Commenters also expressed support for the focused attention on interchangeability, particularly the commitments to develop foundational guidances for the development of interchangeable biosimilar biological products.

Commitments to modernize FDA's information technology infrastructure, continue enhancing financial resource management, and improve hiring and retention of staff were also applauded by the commenters.

One commentor expressed support for the commitment to publish guidance on the use of alternative tools to assess manufacturing facilities named in pending applications and enhancements to inspection communication for applications. Another commentor noted the importance of the use related risk analysis and human factors validation study protocols commitments in BsUFA III.

Other comments

In addition to the broad support offered for BsUFA III, two of the commenters offered additional suggestions. One commenter suggested FDA engage pharmacists and pharmacy organizations in discussions related to the propriety name review performance goals. Another commenter expressed concerns that covid-19 related delays in pre-licensure inspections are adversely impacting on-time actions for original biosimilar biological product applications, including resubmissions. The commenter emphasized that FDA must address the inspectional backlog for BsUFA III to be successful and for public health reasons.

FDA appreciates the input and will consider these comments as it develops its implementation plans, to the extent they are consistent with reauthorization legislation that is passed into law.

Conclusion

FDA greatly appreciates the thoughtful input provided by stakeholders. Given the general support for the BsUFA III agreement, FDA has not made changes to those recommendations for the reauthorization of BsUFA.

Relevant Links

BsUFA III: Fiscal Years 2023-2027: https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iii-fiscal-years-2023-2027

[Federal Register Notice] Reauthorization of the Biosimilar User Fee act; Public Meeting; Request for Comments: https://www.federalregister.gov/documents/2021/09/22/2021-20432/reauthorization-of-the-biosimilar-user-fee-act-public-meeting-request-for-comments