

December 2, 2021

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2015-N-3326: Reauthorization of the Biosimilar User Fee Act; Public Meeting; Request for Comments

To Whom It May Concern:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments on the Food and Drug Administration's (FDA or the Agency) request for comments on the reauthorization of the Biosimilar User Fee Act (BsUFA) for fiscal years (FYs) 2023 through 2027. PhRMA commends FDA for holding the virtual meeting to hear stakeholder views on BsUFA reauthorization.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Over the past 20 years, PhRMA member companies have invested more than \$1 trillion in the search for new treatments and cures, including an estimated \$91.1 billion in 2020 alone.¹

Biosimilars are playing an increasingly critical role in bringing new options to patients and increasing competition. Currently, there are 31 FDA-approved biosimilar products, including two interchangeable biosimilars. In addition, the FDA reported as of June 2021, there are nearly 100 biosimilars in development for which sponsors are paying BsUFA fees and benefiting from BsUFA-supported meetings with FDA.² And while the U.S. has not had a biosimilar market in place as long as the European Union (EU), the U.S. market has significantly evolved over the last decade. In fact, the U.S. has approved more biosimilar products than the EU had in a comparable period of time. This is largely due to the regulatory predictability and efficiencies that have been provided by the FDA's successful implementation of the abbreviated approval pathway for biosimilars and the resources provided through BsUFA.

As a result of growing competition, annualized savings due to biosimilars reached \$6.5 billion in 2020³ and potential savings are estimated to exceed \$100 billion in the aggregate between 2020 and 2024.⁴ Many innovator medicines are now competing with multiple biosimilar

¹ PhRMA, "PhRMA 2021 Annual Membership Survey," (2021), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/PhRMA_membership-survey_2021.pdf

² FDA, "FDA-TRACK: Center for Drug Evaluation & Research - Pre-Approval Safety Review - Biosimilars Dashboard," <https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-center-drug-evaluation-research-pre-approval-safety-review-biosimilars-dashboard>

³ Adam J. Fein, "The Booming Biosimilar Market of 2020," (October 6, 2020), <https://www.drugchannels.net/2020/10/the-booming-biosimilar-market-of-2020.html>

⁴ IQVIA Institute, "Biosimilars in the United States 2020 – 2024," (October 2020), https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/iqvia-institute-biosimilars-in-the-united-states.pdf?_id=1606843358393

versions, with some brand biologics currently facing competition from as many as five biosimilars.

PhRMA has been a strong supporter of, and participant in, BsUFA since its inception in 2012. We appreciate the opportunity to provide the following comments on the BsUFA III Performance Goals letter.⁵

I. BsUFA III WILL ENHANCE FDA’S BIOSIMILAR REVIEW PROCESS WHILE ENSURING STABILITY AND CONTINUED MATURATION OF THE PROGRAM

Through the targeted improvements outlined in the BsUFA III Performance Goals letter,⁶ BsUFA III will build on the success of the program and help increase timely access to safe and effective biosimilar and interchangeable biosimilar products for patients.

1. BsUFA III Will Advance Development of Interchangeable Biosimilar Products and Pilot a Regulatory Science Program

BsUFA III will provide information and guidance to sponsors for development of biosimilar and interchangeable biosimilar products. BsUFA III will also inform FDA’s strategic development of guidances and best practices and procedures. Specifically, FDA will issue guidance on topics foundational for the development of interchangeable biosimilar products while holding a scientific workshop and developing a strategy document on the development of interchangeable products.⁷ FDA will also pilot a regulatory science program with clearly outlined demonstration projects and deliverables focused on advancing the development of interchangeable biosimilar products and improving the efficiency of biosimilar product development.⁸ Stakeholders will be updated on progress of and findings from the demonstration projects through interim and final summary reports and a public meeting which will allow for public engagement and discussion. Informed by the pilot program, FDA will publish a comprehensive strategy document outlining specific actions the Agency will take to facilitate the development of biosimilar and interchangeable biosimilar products.

2. BsUFA III Will Enhance Manufacturing Inspection-related Communications and Modernize Facility Assessment Approaches Based on COVID-19 Lessons Learned

Following the suspension of most foreign and domestic inspections in March 2020 due to the COVID-19 pandemic, FDA has used a number of alternative tools in lieu of in-person inspections. BsUFA III will advance use of alternatives to on-site inspections (e.g., requesting records and other information directly from facilities and other inspected entities, utilizing new or existing technology platforms to assess manufacturing facilities as appropriate) beyond the current public health emergency.⁹ FDA will develop guidance on the use of alternative tools to

⁵ Reauthorization of the Biosimilar User Fee Act; Public Meeting; 86 Fed. Reg. 52685 (September 22, 2021).

⁶ FDA, “BsUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027,” <https://www.fda.gov/media/152279/download> [hereinafter BsUFA III Commitment Letter].

⁷ See BsUFA III Commitment Letter at 29-30.

⁸ *Id.* at 30-31.

⁹ See BsUFA III Commitment Letter at 26.

assess manufacturing facilities named in pending applications, including incorporation of best practices from the use of such tools during the COVID-19 pandemic. In addition, BsUFA III will promote timely FDA communication with sponsors regarding manufacturing facility inspections.¹⁰

3. BsUFA III Will Modernize FDA’s Information Technology (IT) Infrastructure and Support Adoption of Cloud-based Technologies

An efficient and predictable regulatory review process depends on a supportive technology infrastructure. To modernize FDA’s data and IT capacity and capabilities and align with cross-Center efforts, BsUFA III will support cloud-based modernization of the Electronic Submissions Gateway (ESG) with an improved architecture that supports expanding data submission bandwidth and storage.¹¹ BsUFA III will also enhance accountability and transparency in FDA’s IT activities and modernization plans by establishing a strategy on data-driven regulatory initiatives.¹² These initiatives will build on FDA’s ongoing efforts as outlined in the Agency’s Technology Modernization Action Plan (TMAP) and Data Modernization Action Plan (DMAP).

4. BsUFA III Will Build on BsUFA II Efforts to Modernize FDA Financial and Staff Resource Management

BsUFA II included improvements to the financial structure of the BsUFA program¹³ aimed to help ensure financial stability and appropriate staffing for the FDA to meet negotiated goals, with implementation and maturation of these reforms expected to continue into BsUFA III. Implementation of the proposed BsUFA III performance goals¹⁴ will build on the foundational work started in BsUFA II to modernize financial and staff resource management, accountability, and transparency, including clear hiring goals and progress reporting.

5. BsUFA III Also Includes Other Important Commitments

BsUFA III includes specific timelines for review of certain application supplements, including those seeking to update safety labeling to reflect changes to the reference product labeling.¹⁵ BsUFA III also includes modifications to existing meeting types¹⁶ (e.g., modifying the current Biosimilar Initial Advisory (BIA) meeting to permit discussion of demonstration of biosimilarity without a sponsor needing to provide preliminary comparative analytical data) and establishment of a new meeting type for rapid, targeted feedback to enable timely interactions between sponsors and FDA during biosimilar development and review.

¹⁰ *Id.* at 25-26.

¹¹ *Id.* at 35-36.

¹² *Id.* at 35.

¹³ See FDA, “BsUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022,” at 27-32, <https://www.fda.gov/media/100573/download>.

¹⁴ See BsUFA III Commitment Letter at 31-35.

¹⁵ See BsUFA III Commitment Letter at 4-7.

¹⁶ *Id.* at 17-24.

II. CONCLUSION

BsUFA III will play a critical role in improving the predictable, timely and efficient development and regulatory review of biosimilar and interchangeable biosimilar products. PhRMA fully supports both the proposed BsUFA III performance goals as well as a timely legislative reauthorization of BsUFA. PhRMA looks forward to working with FDA, Congress, patient and medical provider groups and other stakeholders to ensure timely reauthorization of this important program and that there are no disruptions to the FDA activities.

Respectfully submitted,

_____/s/_____
Lucy Vereshchagina, PhD,
Vice President, Science and
Regulatory Advocacy

_____/s/_____
Kelly Falconer Goldberg
Vice President, Law/Senior
Counsel for Biopharmaceutical Regulation