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December 18, 2020

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

Dear Sir or Madam:

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) Reauthorization of the Biosimilar User Fee Act (BsUFA). PhRMA commends FDA for holding the virtual meeting to hear stakeholder views on BsUFA as the Agency considers the features to propose, update, and discontinue in BsUFA III.

PhRMA represents America'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 last twenty years, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.[1] PhRMA's membership includes many leading biopharmaceutical companies actively developing biosimilar medicines.

PhRMA supports advancing policies that promote innovation and competition in the biologics and biosimilars marketplace. Currently, there are 18 biosimilar products on the U.S. market competing against 7 reference biologics, with 11 additional FDA-approved biosimilars due to come to market over the next several years.[2] As America's health care system continues to evolve, biosimilars will play an increasingly critical role in bringing new options to patients and decreasing prescription drug spending. Annualized savings from biosimilars reached $6.5 billion in the second quarter of 2020,[3] and savings are modeled to exceed $100 billion in aggregate over the next five years.[4]

Development and approval of safe and effective biosimilars requires a regulatory paradigm that supports an efficient and timely review process and provides scientific and

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[1] PhRMA, "PhRMA 2020 Annual Membership Survey," (2020), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_Membership_Survey_2020.pdf.

[2] PhRMA analysis of Biosimilar Product Information from FDA, https://www.fda.gov/drugs/biosimilars/biosimilar-product-information; 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?_=1606843358393

[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?_=1606843358393

regulatory clarity for sponsors. That is why PhRMA supports a strong, appropriately-staffed, and science-based FDA resourced through a combination of appropriated funds and user fees from the regulated industry. BsUFA has played an essential role in strengthening FDA's ability to implement a regulatory review approach for biosimilar products that supports innovation and is consistent with the Agency's high standards for scientific rigor and patient safety.

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 reauthorization of the BsUFA program.[5]

I. BsUFA HAS BEEN A SUCCESS FOR FDA, INDUSTRY, AND PATIENTS

BsUFA was created to help provide FDA with resources and staffing to support a biosimilar approval pathway and promote greater consistency, certainty, and predictability in the review of biosimilar products. BsUFA II was informed by lessons learned from initial experiences with the program and included initiatives to enhance the biosimilar review model, promote more informative engagement between FDA and biosimilar product developers, and help ensure the long-term sustainability of BsUFA activities.[6]

II. BsUFA III OFFERS THE OPPORTUNITY FOR FURTHER IMPROVEMENTS

BsUFA III offers an opportunity for stakeholders to work together to create a BsUFA program that builds on the successes of the first two cycles by strengthening foundational elements and enhancing regulatory review processes to provide increased efficiency and stability to the program. In addition to BsUFA-specific enhancements, there is also an opportunity to support a coordinated approach to key cross-Center and cross-user fee initiatives underpinning the human drug review program.

1. BsUFA III Can Optimize FDA Staffing and Resources

BsUFA user fees help ensure that the FDA's biosimilar review program is appropriately structured, resourced, and staffed to support the efficient review and licensure of biosimilar products that meet FDA's high standards for biosimilarity with regards to similarity as well as safety, purity and potency and help facilitate future growth in the marketplace of biosimilar and interchangeable products.

BsUFA II included key financial deliverables, including establishing an independent fee structure, development of a resource capacity planning function, and implementation of modernized time reporting, to help enhance management and alignment of BsUFA resources to programmatic needs.[7] Implementation and maturation of these improvements should continue

[5] Reauthorization of the Biosimilar User Fee Act; Public Meeting; 85 Fed. Reg. 68886-68888 (October 30, 2020).

[6] FDA, "BsUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022," https://www.fda.gov/media/100573/download [hereinafter BsUFA II Commitment Letter].

[7] *See* BsUFA II Commitment Letter at 27-29.

in BsUFA III to support predictable user fee funding levels and improve transparency of the program's funding and performance needs at the Agency.

Through BsUFA III, FDA can also adopt continued improvements to processes supporting hiring, recruitment, and retention of staff and key experts, to help ensure the Agency has a strong scientific and medical workforce to advance its public health mission.[8]

2. BsUFA III Can Improve the Information Technology Infrastructure

FDA's centralized administrative services, including its data and information technology infrastructure, help to enable all FDA review activities, and these critical functions are supported by the multiple medical product user fee programs.

Modernizing and enhancing FDA's technological capabilities can help the Agency advance forward-looking data initiatives to improve regulatory review processes, such as the integration of cloud-based technologies. As new technologies continue to accelerate the development of biological products and biosimilars, it is important that FDA is able to effectively and efficiently exchange and process data. BsUFA III can help support a coordinated approach to enterprise-wide initiatives by building on ongoing FDA efforts such as the Technology Modernization Action Plan[9] and implementing a data and technology modernization framework and strategy.

3. BsUFA III Can Further Support Biosimilar and Interchangeable Product Development and Prompt Updates to Safety Information

While BsUFA I[10] and II[11] laid the foundation for the biosimilar review process, select enhancements in BsUFA III could further support biosimilar and interchangeable biosimilar product development and improve review efficiency, including by providing sponsors with more complete guidance related to interchangeable products.[12]

In addition, BsUFA III can facilitate prompt updates to safety information by establishing review timelines for safety labeling updates, so that manufacturers of biosimilar and interchangeable products have a timely and transparent process to update the applicable safety information to reflect relevant, updated safety information for the reference product.

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[8] *See* PhRMA, Comments to Docket FDA-2020-N-1500 (September 30, 2020), https://beta.regulations.gov/comment/FDA-2020-N-1500-0004 for a detailed description of issues to address and enhancements to be made prior to the next user fee reauthorization cycle.

[9] FDA, "FDA's Technology Modernization Action Plan," (September 18, 2019), https://www.fda.gov/media/130883/download.

[10] FDA, "Biosimilar Biological Product Authorization Performance Goals and Procedures Fiscal Years 2013 Through 2017," https://wayback.archive-it.org/7993/20170111191425/http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM281991.pdf.

[11] BsUFA II Commitment Letter.

[12] PhRMA appreciates FDA's efforts to provide guidance related to interchangeable products thus far, including the recent release of the "Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act; Guidance for Industry" (November 19, 2020).

III. CONCLUSION

By focusing on the key areas outlined above, BsUFA III would help ensure FDA has the resources and structure to support science-based review of biosimilars and interchangeable products, which would help increase competition in the marketplace to the benefit of patients and the U.S. healthcare system.

PhRMA looks forward to working collaboratively with FDA and other stakeholders to enhance the existing program and make improvements where appropriate in BsUFA III. The timely reauthorization of the BsUFA program is important to maintain the high level of the biosimilar review program performance, while enhancing the predictable regulatory review framework needed to support future biosimilar investment. PhRMA supports a timely and efficient reauthorization process and expeditious approval in Congress to ensure there are no disruptions to FDA activities.

Respectfully submitted,

_____/s/_____	_____/s/_____	_____/s/_____
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