American Pharmacists Association

Via electronic submission to: www.regulations.gov

December 2, 2021

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

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

Dear Food and Drug Administration Staff:

The American Pharmacists Association (APhA) is pleased to submit our comments to the Food and Drug Administration (FDA) on "Reauthorization of the Biosimilar User Fee Act; Public Meeting; Request for Comments"[1] and the Biosimilar User Fee Act (BsUFA III) draft commitment letter.[2] Founded in 1852, APhA is the largest association of pharmacists in the United States representing the entire pharmacy profession. APhA members practice in community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA supports BsUFA's goal of ensuring the efficiency and effectiveness of the biosimilar biological product review program, as well as enhancing biosimilar and interchangeable biological product development for optimal care and access for patients. Furthermore, APhA supports BsUFA's goal to provide additional revenues so that FDA can hire more staff, improve systems, and continue a well-managed review process to make important biosimilar therapies available to patients sooner without compromising FDA's high standards for safety, efficacy, and quality. APhA offers the following comments on the draft commitment letter:

[1] FDA. Reauthorization of the Biosimilar User Fee Act; Public Meeting; Request for Comments. 86 FR 52685. September 22, 2021. Available at: https://www.govinfo.gov/content/pkg/FR-2021-09-22/pdf/2021-20432.pdf.
[2] FDA. BIOSIMILAR BIOLOGICAL PRODUCT REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2023 THROUGH 2027. (hereinafter "commitment letter"). Available at: https://www.fda.gov/media/152279/download

Review Performance Goals (pp. 4-8)

APhA supports the FDA's efforts to promote efficiency in the review and approval of biosimilar biological products by committing to review and act on 90 percent of original biosimilar biological product applications within 10 months of the 60 day filing date and by accelerating supplement reviews. APhA also supports initiatives included in the commitment letter that will improve first cycle approvals, such as increased communications and meetings between FDA and product sponsors.

Program for Enhanced Review Transparency and Communication for Original 351(k) BLAs (pp. 8-14)

APhA supports the promotion of transparency between FDA review teams and applicants, in part through the outlining of appropriate procedures. This includes parameters and opportunities for a pre-submission meeting, original application submission, Day 74 letter, review performance goals, mid-cycle communications, late-cycle and Advisory Committee meetings, and inspections.

Review of Proprietary Names to Reduce Medication Errors (pp. 14-15)

In order to reduce patient and pharmacist confusion and protect public health, APhA strongly supports FDA's efforts to reduce medication errors related to look-alike and sound-alike proprietary names and such factors as unclear label abbreviations, acronyms, dose designations, and error-prone label and packaging design. Therefore, APhA welcomes the commitment letter's inclusion of performance goals for FDA to review biosimilar biological product proprietary name submissions in order to address potential issues as soon as possible. We encourage inclusion of pharmacists and pharmacy organizations in the discussions related to these performance goals.

Meeting Management Goals (pp. 17-25)

As noted above, APhA supports initiatives included in the commitment letter that will improve the biosimilar approval process, including communications and meetings between FDA and product sponsors. Among others, this includes a new Type 2a meeting to obtain rapid feedback on a focused set of questions; a new mechanism to obtain rapid clarification of meeting minutes; and a program to share best practices related to meeting management.

APhA also supports FDA's commitment to issue a revised draft of the existing draft guidance on "Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products" and to update relevant MAPPs and SOPPs.

Enhancing Biosimilar and Interchangeable Biological Product Development and Regulatory Science (pp. 25-26)

Competition among biological products is incredibly helpful and valuable in driving down drug prices and improving accessibility for patients. Therefore, as discussed throughout these comments, APhA supports FDA's efforts to facilitate the timely development of biosimilar and interchangeable biological products, which pharmacists may substitute for the reference product without the intervention of the prescriber, subject to state laws. This includes FDA's proposal to pilot a regulatory science program focused on enhancing regulatory decision-making and facilitating science-based recommendations in areas foundational to biosimilar and interchangeable biological product development.

Advancing the Development of Biosimilar Biological-Device Combination Products Regulated by CDER and CBER (pp. 26-28)

Use-Related Risk Analysis (URRA) and human factor (HF) validation studies are important to evaluating the user interface of a drug-device or biologic-device combination product to eliminate or mitigate use-related hazards that may affect the safe and effective use of the combination product. APhA supports the new procedures and timelines for URRA and HF validation study protocols, as well as guidance included in the commitment letter that are designed to advance the development of combination products.

Advancing Development of Interchangeable Biosimilar Biological Products (pp. 28-30)

APhA supports the FDA's commitment to advancing the development of safe and effective interchangeable biosimilar biological products. This includes leveraging the BsUFA III Regulatory Science Program to advance product development, issuing foundational guidances, and holding a scientific workshop on the development of interchangeable products to help identify future needs.

Regulatory Science to Enhance the Development of Biosimilar and Interchangeable Biological Products (pp. 30-31)

Because the development of interchangeable biosimilars has the greatest potential to reduce drug costs, APhA supports the two demonstration projects detailed in the commitment letter: (1) advancing the development of interchangeable products, and (2) improving the efficiency of biosimilar product development.

Advancing Development of Interchangeable Products

This demonstration project would:

- Assess the potential impact of differences between proposed interchangeable biosimilar and reference product presentations and container closure systems.
- Predict immunogenicity related to interchangeability.

Improving the Efficiency of Biosimilar Product Development

This demonstration project would:

- Review and evaluate opportunities for streamlining and targeting biosimilar product development
- Predict immunogenicity related to biosimilarity.

APhA also appreciates FDA's commitments to hold a public meeting to review the progress of the demonstration projects and solicit input on future priorities; post a final summary report of outcomes from the demonstration projects on FDA's website; and publish a comprehensive strategy document outlining specific actions the agency will take to facilitate the development of biosimilar and interchangeable biological products. APhA encourages FDA to complete these deliverables as soon as possible during BsUFA III.

Continued Enhancement of User Fee Resource Management (pp. 31-33)

It is critical that FDA continues to be a good steward of its financial resources. APhA is encouraged by FDA's resource capacity planning (RCP) and modernized time reporting implementation to date. Moving forward, we urge FDA to fully enable its RCP capabilities and

to continue to improve its Capacity Planning Adjustment (CPA) methodology to better assess the sustained workload and BsUFA resource needs.

Accordingly, APhA supports FDA's commitments to:

- publish an implementation plan that will describe how the agency's RCP function and time reporting will continue to be implemented during BsUFA III;
- conduct a third-party assessment of the CPA;
- reduce the carryover balance to no greater than 21 weeks of the target revenue by the end of FY 2025; and
- publish an updated BsUFA 5-year financial plan with annual updates and convene an annual public meeting to discuss the 5-year financial plan and FDA's progress in implementing RCP, including the continual improvement of the CPA and time reporting, and the integration of RCP in resource and operational decision-making processes.

Improving FDA Hiring and Retention of Review Staff (pp. 34-35)

APhA supports the BsUFA III commitment letter's focus on hiring and retaining highly qualified review staff. Specifically, APhA supports FDA's:

- Intention to hire 15 new FTEs and report on progress against this hiring goal for BsUFA III on a quarterly basis posting updates to the FDA BsUFA Performance Webpage; and
- Use of a qualified, independent contractor with expertise in assessing HR operations to conduct a targeted assessment of the hiring and retention of staff working for the biosimilar biological product review program.

The goal is to improve the hiring and retention process by understanding factors both within and outside of FDA's control.

Information Technology Goals (pp. 35-36)

APhA supports initiatives included in the commitment letter to modernize FDA's information technology (IT) infrastructure to support BsUFA III goals. These include:

- Development of a Data and Technology Modernization Strategy;
- Resources to monitor and modernize the Electronic Submission Gateway (ESG) transition to the cloud;
- Resources to support reporting and annual sharing of updates that reflect progress and any adjustments needed; and
- FDA's commitment to engage with industry to provide feedback and/or participate in pilot testing in advance of implementing significant changes that impact industry's interaction with the enterprise-wide systems.

Conclusion

APhA appreciates the opportunity to submit these comments on the draft BsUFA III commitment letter. We look forward to continuing to work with FDA, Congress, and other stakeholders as the reauthorization process continues. If you have any questions or need additional information, please feel free to contact Karin Bolte, Director, Health Policy at (202) 558-2727.

Sincerely,

Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs