Public Meeting on the Reauthorization of the Biosimilar User Fee Act (BsUFA)

November 19, 2020

PhRMA
RESEARCH • PROGRESS • HOPE

PhRMA Supports a Strong, Fully Resourced FDA

- PhRMA supports advancing policies that promote innovation and competition in the biologics and biosimilars marketplace
- 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
- Development and approval of safe and effective biosimilar products depends on a fully funded FDA providing timely, science-based regulatory decisions
- FDA is resourced through a combination of appropriated funds and user fees from the regulated industry, which allows the Agency to implement a science-based regulatory approach that ensures patient safety while facilitating a robust biosimilars market

BsUFA Has Been Successful for FDA, Industry, and The Patients We Serve

- BsUFA I helped provide FDA with resources to implement a biosimilar approval pathway and promote greater consistency and predictability in the review of biosimilar products

- BsUFA II commitments enhanced the biosimilar review model, promoted more informative engagement between FDA and sponsors, and helped ensure the long-term sustainability of BsUFA activities

- BsUFA III offers an opportunity to build on the successes of previous BsUFAs by strengthening foundational elements and enhancing regulatory review processes to provide increased efficiency and stability to the program

BsUFA III Can Optimize FDA Staffing and Resources

- BsUFA ensures the foundational aspects of the biosimilar review program are secure and appropriately funded

- The funding and hiring reforms established under BsUFA II can lead to even greater efficiency and sustainability for the program

- BsUFA III can continue to make improvements to:
  - Enhance FDA's capabilities to hire, recruit, and retain staff
  - Ensure continuity of operations through more predictable user fee funding levels
  - Improve transparency of the program's funding and performance needs at the Agency

BsUFA III Can Improve the Information Technology Infrastructure

- Information technology is a critical component to the success of FDA's review programs
- FDA will need to modernize the ongoing technological efforts to accommodate new data and technology initiatives, such as cloud-based submissions
- BsUFA III can help support a coordinated approach to cross-Center and cross user fee initiatives and build on ongoing efforts to establish a formal data and technology modernization framework

BsUFA III Can Further Support Biosimilar Product Development and Patient Safety

- While BsUFA I and II laid the foundation for the biosimilar review process, select enhancements could further support biosimilar product development, improve review efficiency, and enhance patient safety

- BsUFA III offers an opportunity to:
  - Provide sponsors with more complete guidance related to interchangeable products, and
  - Establish review timelines for biosimilar product safety labeling updates

Conclusion - Thank You

- BsUFA III can help ensure FDA has the resources to support science-based review of biosimilars, which will help increase competition in the marketplace to the benefit of patients
- 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