# Reauthorization of the Biosimilars User Fee Act Public Meeting

November 19, 2020

Biotechnology Innovation Organization

# Biotechnology Innovation Organization

- BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations.

- BIO member companies range from small start-ups and companies with one or only a few FDA-approved products, to some of the largest biopharmaceutical companies in the world.

- These companies share a commitment to bring innovation to patients and to work at the cutting edge of technology to achieve that goal.  They also share an unwavering dedication to improving health and healthcare in the face of a very high risk of failure.

# The BsUFA Program Is Critical to Promoting Competition in the Biologics and Biosimilars Marketplace

- BIO and its member companies support advancing policies that promote innovation and competition in the biologics and biosimilars marketplace
- BIO supports ensuring FDA has the resources and expertise needed to support timely and scientifically-based development and review processes for biosimilars
- BsUFA is critical to providing funding for the biosimilar review program
- BsUFA III offers the opportunity to build off the successes of BsUFA I and II which provided important funding, hiring and meeting management reforms
  - We will be looking for ways to improve the efficiency of the program to better benefit patients and enhance biosimilar development programs.
- BIO looks forward to working collaboratively with FDA to ensure a timely reauthorization of this important program.

# BsUFA III Priorities – Patient Centric & Effective

**BsUFA III Priorities**

- **Making Targeted Improvements to Support Product Development**
- **Improving FDA/Sponsor Interactions**
- Hiring & Resource Management Accountability
- Data and Technology Infrastructure and Modernization

# Targeted Improvements To Support Product Development

- In BsUFA II, FDA committed to ensuring the effectiveness of the biosimilar biological product review program.
- BsUFA III offers an opportunity to develop even more efficient and effective review and approval of biosimilars.
- We look forward to discussing how we can work to:
  - Define review timelines for Sponsors for prior approval supplements (PAS), and
  - Clarify reporting categories for post-approval changes in chemistry, manufacturing and controls (CMC).

# Enhancing Scientific Dialogue Between FDA and Sponsors

- The growth and evolution of the BsUFA program has resulted in greater need for earlier and more frequent interaction.

- Appropriate communication and early/effective engagement between the FDA and Sponsors is integral to ensure the efficiency and rigor of biosimilar development programs

# Enhancing Scientific Dialogue Between FDA and Sponsors

- BsUFA III offers an opportunity to continue to improve scientific dialogue between Industry and the FDA and enable engagement processes that are iterative, timely, and effective.

- We look forward to discussing how we can work to:
  - Establish processes and best practices that would improve efficiency and effectiveness of FDA-Sponsor meetings.
  - Establish a mechanism for Sponsors to receive more timely feedback to targeted biosimilar development questions to ensure clarity and improve efficiency.

# Thank You

- BsUFA III can help ensure the timely and science-based review of biosimilars which is critical to promoting innovation and competition in the biologics and biosimilars marketplace

- We look forward to continuing to work with FDA and other stakeholders to ensure a timely reauthorization of BsFUA III that achieves these goals and maintains the high standards of the review program.