BIOSIMILARS COUNCIL
A DIVISION OF AAM

# The Biosimilar Approval Pathway and BsUFA III

## How do Biosimilars receive market approval?

Under FDA's biosimilar review pathway, manufacturers must submit a biologics license applications (BLA) to the FDA's Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research.

For FDA approval, BLAs must demonstrate the biosimilar is "highly similar" to the reference biologic product and that there are no clinically meaningful differences in safety, purity or potency.

**2015**
YEAR THE FIRST BIOSIMILAR IS APPROVED

**30+**
FDA-APPROVED BIOSIMILARS, AS OF JANUARY 2022, WITH DOZENS MORE IN THE QUEUE

## How is this review process funded?

Along with congressional appropriations, FDA's biosimilar review pathway is largely funded by user fees collected from manufacturers. The **Biosimilar User Fee Act (BsUFA)** authorizes FDA to assess and collect fees from manufacturers that submit BLAs for review.

A BsUFA authorization lasts five years. Subsequent reauthorization requires industry and FDA negotiations. In the past two reauthorizations, negotiations focused on enhancing and improving the review process to facilitate timely access to biosimilar medicines.

## Who participates in the BsUFA reauthorization process?

**FDA Convenes Public Meetings**
Held before negotiations for the BsUFA program and at end of negotiations to solicit stakeholder feedback

**FDA and Industry Negotiate BsUFA Commitment Letter**
Process establishes terms of BsUFA commitment letter, specifying overall program cost, performance goals and more

**Public Meeting Follows Release of Commitment Letter**
Once negotiated commitment letter is drafted, FDA holds public meeting where stakeholders can evaluate and comment on commitment letter

**Commitment Letter Submitted to Congress**
Final commitment letter is submitted to Congress for ratification; FDA cannot begin collecting user fees until reauthorization is signed into law

## With BsUFA II set to expire in October 2022, what commitments has the FDA identified for BsUFA III?

- **Biosimilar Application Supplements –** Accelerate review for modifications to approved BLAs
- **Meeting Management –** Meet with BLA sponsors to facilitate a predictable and efficient review process
- **Interchangeability & Regulatory Science Program –** Help manufacturers develop more interchangeable biosimilars through new demonstration projects under the regulatory science program
- **Use-Related Risk Analysis (URRA) –** Publish draft guidance by 2024 to help biosimilar manufacturers conduct comprehensive URRAs to identify and mitigate risks associated with how end users use products
- **Inspections –** Issue guidance on the use of alternative inspection tools to assess manufacturing facilities, incorporating best practices from the COVID-19 pandemic
- **Spend-Down of Carryover Funds –** Reduce carryover balance from user fees collected but not spent from 39 weeks to 21 weeks

Learn more about the Biosimilars Council, leading on biosimilars for America's patients: **biosimilarscouncil.org**