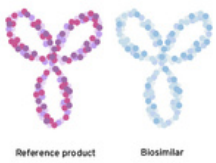
Biocom California
BsUFA III



The Biologic Price Competition and Innovation Act of 2009 (BPCIA) created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. The authority to collect user fees was provided by the Biosimilar User Fee Act of 2012 (BsUFA). In exchange, FDA is obligated to meet performance goals negotiated with industry. BsUFA is reauthorized every five years.

The BsUFA III user fee base revenue amount for FY 2023 is $43.4 million. The FY 2023 fees and their respective rates are as follows: the initial and annual Biosimilar Biological Product Development (BPD) fee ($47,325), the reactivation fee ($94,650), an application requiring clinical data ($1,746,745), an application not requiring clinical data ($873,373), and the program fee ($304,162). When compared to FY 2022, the BPD user fee amounts decreased for FY 2023 while the application and program fees remained the same.

Legislative History:

2012: The Biosimilar User Fee Act is signed into law. BsUFA I authorized the FDA to collect fees directly from drug product sponsors to expedite the approval of biosimilar applications

2017: BsUFA II is signed into law through the FDA Reauthorization Act.

2022: BsUFA III is signed into law as part of the Continuing Appropriations and Ukraine Supplemental Appropriations Act. This bill reauthorized the program for 5 years until FY 2027.

Accomplishments: as of September 30, 2022

177 programs enrolled in the BPD Program (since October 2015)

39 biosimilar products approved

2 interchangeable biosimilars for insulin

Biocom California

Highlights of BsUFA III:

Regulatory Science Pilot Program

The pilot program is focused on improving the efficiency of biosimilar product development and advancing the development of interchangeable products. FDA will host a public meeting to review the pilot program's progress by FY 2025 and publish a report by FY 2027.

Data and Technology Modernization

As part of FDA's Technology and Data Modernization Action Plans, FDA will establish a modernization strategy and transition to a cloud platform to facilitate sponsor access to Agency resources.

Hiring

FDA plans to hire 15 additional staff for the biosimilar biological product review program by the end of FY 2024.

Interchangeable Products

FDA will host a workshop on interchangeable product development to identify future needs and publish and seek feedback on a draft strategy in FY 2026 to facilitate interchangeable product development. FDA will also publish draft guidance for labeling and promotional advertising considerations for interchangeable biosimilars by FY 2024.

Performance Goals

FDA has committed to reviewing BsUFA products on the following:

- 90% of Category A biosimilar supplements reviewed within 3 months
- 90% of Category B and C biosimilar supplements reviewed within 4 months
- 90% of Category D biosimilar supplements reviewed within 6 months
- 90% of BPD Type 2a meetings held or issued a written response
- 90% of filed submissions reviewed and provided agreement or non- agreement with comments within 60 days
- 90% of human factors validation protocol submissions reviewed and provided written comments within 60 days

Guidance Documents

FDA has committed to developing the following guidances:

- Guidance describing considerations related to biosimilar biologic-device combination products
- Draft guidance on promotional labeling and advertising considerations for interchangeable biosimilars
- Draft guidance on the type of information to be provided to support post-approval manufacturing changes to approved biosimilars
- Draft guidance describing considerations for developing presentations, container closure systems, and device constituent parts for proposed interchangeable biosimilars.
- Revised draft of the guidance "Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products"

Timeline Highlights:

Starting October 1, 2022

- FDA pilots a regulatory science program to facilitate biosimilar and interchangeable biological product development.
- FDA's electronic submission gateway (ESG) transition to the cloud begins.
- A Data and Technology Modernization Strategy is established

Starting March 31, 2023

- A 5-year BsUFA financial plan is published.

Starting October 1, 2024

- FDA publishes metrics regarding the new Type 2a meeting and requests for face-to-face meetings for the first two years of BsUFA III.

Starting September 30, 2027

The FDA will have completed the following BsUFA III commitments:

- Technology Modernization: A Data and Technology Modernization Strategy and an ESG transition to the cloud to streamline stakeholder access to FDA resources.
- Guidance Documents: 5 guidance documents on BsUFA products
- Regulatory Science Pilot Program: Public meeting and report on the pilot program
- Interchangeable Products: A workshop on interchangeable product development to identify the industry's needs and a draft strategy of FDA actions aimed at facilitating interchangeable biological product development.

SOURCES:

https://www.fda.gov/media/152279/download
https://www.federalregister.gov/documents/2022/10/07/2022-21965/biosimilar-user-fee-rates-for-fiscal-year-2023