FY 2022

Real Time Report

pursuant to the

Biosimilar User Fee Act

as amended by the FDA Reauthorization Act of 2017

Acronyms

BLA – Biologics License Application

BsUFA – Biosimilar User Fee Act

CBER – Center for Biologics Evaluation and Research

CDER – Center for Drug Evaluation and Research

FD&C Act – Federal Food, Drug, and Cosmetic Act

FDA – Food and Drug Administration

FDARA – FDA Reauthorization Act of 2017

FY – Fiscal Year (October 1 to September 30)

Q1 – Quarter 1 (October 1 to December 31)

Q2 – Quarter 2 (January 1 to March 31)

Q3 – Quarter 3 (April 1 to June 30)

Q4 – Quarter 4 (July 1 to September 30)

Background

On August 18, 2017, the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52) was signed into law. FDARA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to revise and extend the user fee programs for human drugs, biologics, generic drugs, medical devices, and biosimilar biological products.

Section 744I(a)(3) of the FD&C Act, as amended by Section 903 of FDARA, requires the Food and Drug Administration (FDA) to provide 'Real Time' reporting, posted on a quarterly basis, of guidance documents and public meetings pertaining to the process for the review of biosimilars.

Real Time Reporting Under Section 744I(a)(3) of the FD&C Act

This report provides the BsUFA real time reporting metrics, required under Section 744I(a)(3) of the FD&C Act, as in effect on September 30, 2022[1]:

> Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary of Health and Human Services shall post on the internet website of the Food and Drug Administration:
>
> 1) The number and titles of draft and final guidance on topics related to the process for the review of biosimilars, and whether such guidances were required by statute or pursuant to a commitment under the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017.
> 2) The number and titles of public meetings held on topics related to the process for the review of biosimilars, and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017.

[1] Effective October 1, 2022, section 744I(a)(3) of the FD&C Act was slightly amended by the Biosimilar User Fee Amendments of 2022, as enacted under title IV of Division F (FDA User Fee Reauthorization Act of 2022) of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Public Law 117-180).

Biosimilars

Guidance Documents

Pursuant to Section 744I(a)(3) of the FD&C Act, this section lists the number and titles of draft and final guidance on topics related to the process for the review of biosimilars, and whether such guidances were required by statute or pursuant to a commitment under the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017. Guidance documents are listed by the quarter in which they were issued and are provided in a cumulative format for Fiscal Year (FY) 2022.

Table 1: Draft and Final Guidance Documents Related to the Process for the Review of Biosimilars for FY 2022

Number	Quarter Issued	Title & Website Link	Date Issued	Issued as Required by Statute or Pursuant to Commitment Letter	Statutory or Commitment Letter Citation (if applicable)
1	Q4	Conducting Remote Regulatory Assessments Questions and Answers; Draft Guidance for Industry www.fda.gov/media/160173/download	7/22/2022	N/A	N/A

Public Meetings

Pursuant to Section 744I(a)(3) of the FD&C Act, the table below lists the number and titles of public meetings held on topics related to the process for the review of biosimilars, and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017. Public meetings are listed by the quarter in which they were held and are provided in a cumulative format for FY 2022.

Table 2: Public Meetings Held Related to the Process for the Review of Biosimilars for FY 2022

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	Public Meeting on the Recommendations for Biosimilar User Fee Act (BsUFA) Reauthorization www.fda.gov/drugs/news-events-human-drugs/public-meeting-recommendations-biosimilar-user-fee-act-bsufa-reauthorization-11022021-11022021	11/2/2021	Held as Required by Statute
2	Q2	Public Meeting: Final Assessment of the Program for Enhanced Review Transparency and Communication in the Biosimilar User Fee Act www.fda.gov/drugs/news-events-human-drugs/public-meeting-final-assessment-program-enhanced-review-transparency-and-communication-biosimilar	3/22/2022	Pursuant to Commitment Letter
3	Q3	Biosimilars: A Decade of Experience and Future Directions—Strategies for Improving Biosimilar Adoption and the Potential Role of Clinical Pharmacology www.fda.gov/drugs/news-events-human-drugs/biosimilars-decade-experience-and-future-directions-strategies-improving-biosimilar-adoption-and	4/13/2022	N/A
4	Q3	2022 Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments www.fda.gov/drugs/news-events-human-drugs/2022-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act	6/7/2022	Pursuant to Commitment Letter
5	Q4	FDA Workshop: Increasing the Efficiency of Biosimilar Development Programs www.fda.gov/drugs/news-events-human-drugs/fda-workshop-increasing-efficiency-biosimilar-development-programs-09192022/	9/19/2022	N/A