



FDA U.S. FOOD & DRUG
ADMINISTRATION

FY 2023

Real Time Report

pursuant to the

Federal Food, Drug, and Cosmetic Act

as amended by the Biosimilar User Fee Amendments of 2022

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

FDAUFRA 2022 – FDA User Fee Reauthorization Act of 2022

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 September 30, 2022, the FDA User Fee Reauthorization Act of 2022 (FDAUFRA 2022) (Public Law 117-180) was signed into law. FDAUFRA 2022 amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by revising and extending 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 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:

Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under BsUFA, 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 2022.
- 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 2022.

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 2022. Guidance documents are listed by the quarter in which they were issued and are provided in a cumulative format for Fiscal Year (FY) 2023.

Table 1: Draft and Final Guidance Documents Related to the Process for the Review of Biosimilars for FY 2023

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	Q1	Comparability Protocols for Post approval Changes to the Chemistry, Manufacturing, and Controls Information in an NDA, ANDA, or BLA; Final Guidance for Industry www.fda.gov/media/162263/download	10/14/2022	No	N/A
2	Q2	Q13 Continuous Manufacturing of Drug Substances and Drug Products; Final Guidance for Industry www.fda.gov/media/165775/download	3/1/2023	No	N/A
3	Q2	Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting Viral Pathogens; Draft Guidance for Industry www.fda.gov/media/165746/download	3/2/2023	No	N/A
4	Q2	Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers; Draft Guidance for Industry www.fda.gov/media/166215/download	3/15/2023	No	N/A
5	Q3	Decentralized Clinical Trials for Drugs, Biological Products, and Devices; Draft Guidance for Industry www.fda.gov/media/167696/download	5/3/2023	Yes	Section 3606(a) of the Food and Drug Omnibus Reform Act of 2022
6	Q3	Generally Accepted Scientific Knowledge in Applications for Drug and Biological Products: Nonclinical Information; Draft Guidance for Industry www.fda.gov/media/168408/download	5/24/2023	No	N/A
7	Q3	Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biological Products; Final Guidance for Industry www.fda.gov/media/148910/download	5/26/2023	No	N/A

Public Meetings

Pursuant to Section 744I(a)(3) of the FD&C Act, this section 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 2022. Public meetings are listed by the quarter in which they were held and are provided in a cumulative format for FY 2023.

Table 2: Public Meetings Held on Topics Related to the Process for the Review of Biosimilars for FY 2023

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q3	Electronic Systems, Electronic Records, and Electronic Signatures Webinar www.fda.gov/drugs/news-events-human-drugs/electronic-systems-electronic-records-and-electronic-signatures-webinar-04252023	4/25/2023	N/A
2	Q3	Regulatory Education for Industry (REdI) Annual Conference 2023 www.fda.gov/drugs/news-events-human-drugs/regulatory-education-industry-redi-annual-conference-2023-06052023	6/5/2023 – 6/9/2023	N/A
3	Q3	2023 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/2023-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act	6/8/2023	Pursuant to Commitment Letter
4	Q3	Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches; Public Workshop www.federalregister.gov/documents/2023/04/24/2023-08545/advancing-the-utilization-and-supporting-the-implementation-of-innovative-manufacturing-approaches	6/8/2023	N/A
5	Q3	Decentralized Clinical Trials (DCT) Draft Guidance www.fda.gov/drugs/news-events-human-drugs/decentralized-clinical-trials-dct-draft-guidance-06202023	6/20/2023	N/A