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 (FDORA)
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

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)
8	Q4	CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality; Final Guidance for Industry www.fda.gov/media/121305/download	7/26/2023	No	No
9	Q4	Assessing User Fees Under the Biosimilar User Fee Amendments of 2022; Final Guidance for Industry www.fda.gov/media/170634/download	7/31/2023	No	N/A
10	Q4	QTc Information in Human Prescription Drug and Biological Product Labeling; Draft Guidance for Industry www.fda.gov/media/170814/download	8/8/2023	No	N/A
11	Q4	Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products; Draft Guidance for Industry www.fda.gov/media/113913/download	8/11/2023	Yes	Section I.H.6.a of BsUFA III Commitment Letter
12	Q4	Classification Categories for Certain Supplements Under BsUFA III; Draft Guidance for Industry www.fda.gov/media/170906/download	8/11/2023	Yes	Section I.C of BsUFA III Commitment Letter
13	Q4	Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products; Final Guidance for Industry www.fda.gov/media/171667/download	8/31/2023	Yes	21st CC, Section 3022 (e)(3) and FDORA, Section 3629(a)
14	Q4	Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989; Final Guidance for Industry www.fda.gov/media/172038/download	9/15/2023	No	N/A
15	Q4	Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act (Revision 1); Draft Guidance for Industry www.fda.gov/media/172169/download	9/18/2023	No	N/A
16	Q4	Labeling for Biosimilar and Interchangeable Biosimilar Products; Draft Guidance for Industry www.fda.gov/media/172170/download	9/18/2023	Yes	Section II.D.2.b of BsUFA III Commitment Letter
17	Q4	Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies; Final Guidance for Industry www.fda.gov/media/172258/download	9/21/2023	No	N/A
18	Q4	Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications; Draft Guidance for Industry www.fda.gov/media/172290/download	9/22/2023	Yes	Section II.B.2. of BsUFA III Commitment Letter

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
6	Q4	Increasing the Efficiency of Biosimilar Development Programs--Reevaluating the Need for Comparative Clinical Efficacy Studies www.fda.gov/drugs/news-events-human-drugs/increasing-efficiency-biosimilar-development-programs-reevaluating-need-comparative-clinical	9/12/2023-9/13/2023	N/A
7	Q4	FDA/PQRI Workshop on the Regulatory Framework for the Utilization of Artificial Intelligence in Pharmaceutical Manufacturing www.fda.gov/drugs/fdapqri-workshop-regulatory-framework-utilization-artificial-intelligence-pharmaceutical	9/26/2023-9/27/2023	No