FY 2024

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) 2024.

Table 1: Draft and Final Guidance Documents Related to the Process for the Review of Biosimilars for FY 2024

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	Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities; Draft Guidance for Industry www.fda.gov/media/173286/download	10/26/2023	No	N/A
2	Q1	Translation of Good Laboratory Practice Study Reports: Questions and Answers; Draft Guidance for Industry www.fda.gov/media/173989/download	11/22/2023	No	N/A
3	Q1	Advanced Manufacturing Technologies Designation Program; Draft Guidance for Industry www.fda.gov/media/174651/download	12/13/2023	No	N/A
4	Q1	Data Standards for Drug and Biological Product Submissions Containing Real-World Data; Final Guidance for Industry www.fda.gov/media/153341/download	12/22/2023	No	N/A
5	Q1	Real-World Data: Assessing Registries To Support Regulatory Decision-Making for Drug and Biological Products; Final Guidance for Industry www.fda.gov/media/154449/download	12/22/2023	No	N/A
6	Q1	Quality Considerations for Topical Ophthalmic Drug Products; Draft Guidance for Industry www.fda.gov/media/172937/download	12/27/2023	No	N/A
7	Q2	Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products; Draft Guidance for Industry www.fda.gov/media/175746/download	1/30/2024	No	N/A
8	Q2	Use of Data Monitoring Committees in Clinical Trials; Draft Guidance for Industry www.fda.gov/media/176107/download	2/13/2024	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)
9	Q2	Charging for Investigational Drugs Under an IND: Questions and Answers; Final Guidance for Industry www.fda.gov/media/176308/download	2/14/2024	No	N/A
10	Q2	Key Information and Facilitating Understanding in Informed Consent Guidance for Sponsors, Investigators, and Institutional Review Boards; Draft Guidance for Industry www.fda.gov/media/176663/download	3/1/2024	No	N/A
11	Q2	Q2(R2) Validation of Analytical Procedures; Final Guidance for Industry www.fda.gov/media/161201/download	3/6/2024	No	N/A
12	Q2	Q14 Analytical Procedure Development; Final Guidance for Industry www.fda.gov/media/161202/download	3/7/2024	No	N/A
13	Q2	Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products; Draft Guidance for Industry www.fda.gov/media/177128/download	3/21/2024	No	N/A
14	Q3	Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers; Draft Guidance for Industry www.fda.gov/media/134862/download	4/24/2024	Yes	BSUFA III commitment letter, Section II.D.2.c.
15	Q3	REMS Logic Model: A Framework to Link Program Design With Assessment; Draft Guidance for Industry www.fda.gov/media/178291/download	5/7/2024	Yes	PDUFA VII M.1.a.
16	Q3	Q&A Manufacturing and Testing Controls for Ophthalmic Sterility www.fda.gov/drugs/guidances-drugs/questions-and-answers-current-good-manufacturing-practice-regulations-production-and-process#23	5/24/2024	No	N/A
17	Q3	Processes and Practices Applicable to Bioresearch Monitoring Inspections; Draft Guidance for Industry www.fda.gov/media/179027/download	6/5/2024	No	N/A
18	Q3	Considerations in Demonstrating Interchangeability With a Reference Product: Update; Draft Guidance for Industry www.fda.gov/media/179456/download	6/21/2024	No	N/A
19	Q3	Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies; Draft Guidance for Industry www.fda.gov/media/179593/download	6/26/2024	Yes	FDORA Section 3604

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 2024.

Table 2: Public Meetings Held on Topics Related to the Process for the Review of Biosimilars for FY 2024

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	2023 NanoDay Symposium: Continuous Manufacturing of Nanomaterials www.fda.gov/drugs/news-events-human-drugs/2023-nanoday-symposium-continuous-manufacturing-nanomaterials-10112023	10/11/2023	No
2	Q1	BsUFA III Regulatory Science Pilot Program www.fda.gov/drugs/news-events-human-drugs/bsufa-iii-regulatory-science-pilot-program-10162023	10/16/2023	No
3	Q1	FDA | CTTI Meeting on Mitigating Clinical Study Disruptions During Disasters and Public Health Emergencies www.fda.gov/drugs/news-events-human-drugs/fdactti-meeting-mitigating-clinical-study-disruptions-during-disasters-and-public-health-emergencies	10/18/2023-10/19/2023	FDORA 3605
4	Q1	Pharmaceutical Quality Symposium 2023: Quality, Supply Chain & Advanced Manufacturing www.fda.gov/drugs/news-events-human-drugs/pharmaceutical-quality-symposium-2023-quality-supply-chain-advanced-manufacturing-10312023	10/31/2023-11/1/2023	No
5	Q1	Common Issues with SEND Data Submitted for Safety Pharmacology Studies www.fda.gov/drugs/news-events-human-drugs/common-issues-send-data-submitted-safety-pharmacology-studies-11162023	11/16/2023	No
6	Q1	Toward Global IDMP Implementation: A Focus on Global Use Cases www.fda.gov/drugs/news-events-human-drugs/toward-global-idmp-implementation-focus-global-use-cases-11282023	11/28/2023	No
7	Q1	FDA | CTTI Public Workshop to Enhance Clinical Study Diversity www.fda.gov/drugs/news-events-human-drugs/discussing-approaches-enhance-clinical-study-diversity-public-workshop-11292023	11/29/2023-11/30/2023	FDORA 3603
8	Q1	Navigating Complex Waters: A Deep Dive into FDA Drug Interactions Guidances and Resources www.fda.gov/drugs/news-events-human-drugs/navigating-complex-waters-deep-dive-fda-drug-interactions-guidances-and-resources-12122023	12/12/2023-12/13/2023	No

9	Q2	Building Quality into the Design and Conduct of Clinical Studies: Integrating Quality by Design (QbD) and Risk-Based Monitoring (RBM) Approaches www.fda.gov/drugs/news-events-human-drugs/building-quality-design-and-conduct-clinical-studies-integrating-quality-design-qbd-and-risk-based	1/31/2024	No
10	Q2	Product Quality Research Institute (PQRI) Workshop: MIDD Approaches in Pediatric Formulation Development www.fda.gov/drugs/news-events-human-drugs/product-quality-research-institute-pqri-workshop-midd-approaches-pediatric-formulation-development	2/28/2024-2/29/2024	No
11	Q3	2024 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/2024-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act	6/6/2024	No
12	Q3	Reddit AMA today on biosimilars in the r/medicine subreddit forum to provide education and outreach to the medical community in that space www.reddit.com/r/medicine/comments/1d8rg19/im_sarah_yim director_for_the_office_of/	6/6/2024	No
13	Q3	OSIS Workshop: CDER Bioavailability/Bioequivalence Study Sites and Inspections of Good Laboratory Practice www.fda.gov/drugs/news-events-human-drugs/osis-workshop-cder-bioavailabilitybioequivalence-study-sites-and-inspections-good-laboratory	6/13/2024	No