FY 2026

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 Amendments

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) (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

Summary

This section provides a summary of the total numbers for each category contained in this report, for certain activities as they relate to the process for the review of biosimilars, within the current fiscal year (FY) as of September 30, 2026.

Category	Total
Guidance Documents	21
Public Meetings	3

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 FY 2026.

Table 1: Draft and Final Guidance Documents Related to the Process for the Review of Biosimilars for FY 2026

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	Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies; Draft Guidance for Industry www.fda.gov/media/189366/download	10/29/2025	No	N/A
2	Q1	Q3E Guideline for Extractables and Leachables: Supporting Documentation: Class 3 Leachable Monographs; Draft Guidance for Industry www.fda.gov/media/189891/download	11/28/2025	No	N/A
3	Q1	Q3E Guideline for Extractables and Leachables; Draft Guidance for Industry www.fda.gov/media/189890/download	11/28/2025	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)
4	Q1	Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers; Final Guidance for Industry www.fda.gov/media/134862/download	12/09/2025	Yes	BsUFA III Commitment; II.D.2.c.
5	Q2	E22 General Considerations for Patient Preference Studies; Draft Guidance for Industry www.fda.gov/media/190946/download	02/06/2026	No	N/A
6	Q2	E2D(R1) Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports; Final Guidance for Industry www.fda.gov/media/176977/download	03/03/2026	No	N/A
7	Q2	M14 General Principles on Planning, Designing, Analyzing, and Reporting of Non-interventional Studies That Utilize Real-World Data for Safety Assessment of Medicines; Final Guidance for Industry www.fda.gov/media/179795/download	03/03/2026	No	N/A
8	Q2	Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection; Draft Guidance for Industry www.fda.gov/media/191427/download	03/06/2026	No	N/A
9	Q2	New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 4): Draft Guidance for Industry www.fda.gov/media/119278/download	03/09/2026	No	N/A
10	Q2	Questions and Answers on Biosimilar Development and the BPCI Act (Revision 3) www.fda.gov/media/119258/download	3/09/2026	No	N/A
11	Q2	Pyrogen and Endotoxins Testing: Questions and Answers: Final Guidance for Industry www.fda.gov/media/83477/download	03/18/2026	No	N/A
12	Q2	General Considerations for the Use of New Approach Methodologies in Drug Development: Draft Guidance for Industry www.fda.gov/media/191589/download	03/18/2026	No	N/A
13	Q3	Submitting Continuous Glucose Monitoring Data in Clinical Trials www.fda.gov/media/192367/download	05/06/2026	No	N/A
14	Q3	Postapproval Pregnancy Safety Studies www.fda.gov/media/124746/download	05/08/2026	No	N/A
15	Q3	Q8, Q9, and Q10 Questions and Answers (R5) www.fda.gov/media/78668/download	05/29/0206	No	N/A
16	Q3	M15 General Principles for Model-Informed Drug Development www.fda.gov/media/184747/download	06/02/2026	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)
17	Q3	Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Questions and Answers: Draft Guidance for Industry www.fda.gov/media/133620/download	06/02/2026	No	N/A
18	Q3	Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products: Draft Guidance for Industry www.fda.gov/media/133660/download	06/24/2026	No	N/A
19	Q3	Master Protocols for Drug and Biological Product Development www.fda.gov/media/174976/download	06/24/2026	No	N/A
20	Q4	Biosimilar and Interchangeable Biosimilar Products: Considerations for Container Closure Systems and Device Constituent Parts www.fda.gov/media/193917/download	08/03/26	Yes	D.2
21	Q4	Container Closure Systems for Human Drugs and Biological Products www.fda.gov/media/194220/download	08/13/2026	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 2026.

Table 2: Public Meetings Held on Topics Related to the Process for the Review of Biosimilars for FY 2026

Number	Quarter Held	Title	Date Held	Held as Required by Statute or Pursuant to Commitment Letter
1	Q1	Public Meeting on the Reauthorization of the Biosimilar User Fee Act (BsUFA) www.fda.gov/industry/public-meeting-reauthorization-biosimilar-user-fee-act-bsufa-12032025	12/3/2025	Yes
2	Q1	Quality and Regulatory Predictability: Shaping USP Standards www.fda.gov/drugs/news-events-human-drugs/quality-and-regulatory-predictability-shaping-usp-standards-12112025	12/11/2025	No

3	Q3	Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments https://www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and-1	6/23/2026	Yes