



**FDA** U.S. FOOD & DRUG  
ADMINISTRATION

# **FY 2025**

## ***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***

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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

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## 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, 2025.

**Table 1: Total Number of Guidance Documents and Public Meetings as of September 30, 2025**

| Category           | Total |
|--------------------|-------|
| Guidance Documents | 8     |
| Public Meetings    | 10    |

## 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 2025.

**Table 2: Draft and Final Guidance Documents Related to the Process for the Review of Biosimilars for FY 2025**

| 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             | Advanced Manufacturing Technologies Designation Program; Final Guidance for Industry<br><a href="http://www.fda.gov/media/174651/download">www.fda.gov/media/174651/download</a>                                         | 12/31/2024  | Yes                                                            | FD&C Act section 506L                                   |
| 2      | Q2             | Considerations for Complying with 21 CFR 211.110; Draft Guidance for Industry<br><a href="http://www.fda.gov/media/184825/download">www.fda.gov/media/184825/download</a>                                                | 1/6/2025    | No                                                             | N/A                                                     |
| 3      | Q2             | Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products<br><a href="http://www.fda.gov/media/184830/download">www.fda.gov/media/184830/download</a> | 1/6/2025    | No                                                             | N/A                                                     |
| 4      | Q3             | Q1 Stability Testing of Drug Substances and Drug Products; Draft Guidance for Industry<br><a href="http://www.fda.gov/media/187161/download">www.fda.gov/media/187161/download</a>                                       | 6/23/2025   | 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) |
|--------|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|----------------------------------------------------------------|---------------------------------------------------------|
| 5      | Q4             | Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Biosimilar User Fee Act Products<br><a href="http://www.fda.gov/media/113913/download">www.fda.gov/media/113913/download</a>                                 | 7/21/2025   | No                                                             | N/A                                                     |
| 6      | Q4             | Classification Categories for Certain Supplements Under BsUFA III; Final Guidance for Industry<br><a href="http://www.fda.gov/media/170906/download">www.fda.gov/media/170906/download</a>                                                          | 9/9/2025    | Yes                                                            | BsUFA III Section II.D.2.d                              |
| 7      | Q4             | Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations; Final Guidance for Industry<br><a href="http://www.fda.gov/media/159261/download">www.fda.gov/media/159261/download</a> | 9/9/2025    | No                                                             | N/A                                                     |
| 8      | Q4             | Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications; Final Guidance for Industry<br><a href="http://www.fda.gov/media/172290/download">www.fda.gov/media/172290/download</a>                              | 9/11/2025   | Yes                                                            | BsUFA III section II.B.2                                |

## 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 2025.

**Table 3: Public Meetings Held on Topics Related to the Process for the Review of Biosimilars for FY 2025**

| Number | Quarter Held | Title                                                                                                                                                                                                                                                                                                                                                                                            | Date Held  | Held as Required by Statute or Pursuant to Commitment Letter |
|--------|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------------------------------------------------------------|
| 1      | Q1           | Global IDMP Implementation - Getting Closer to the Goal<br><a href="http://www.fda.gov/drugs/news-events-human-drugs/global-idmp-implementation-getting-closer-goal-10162024">www.fda.gov/drugs/news-events-human-drugs/global-idmp-implementation-getting-closer-goal-10162024</a>                                                                                                              | 10/16/2024 | No                                                           |
| 2      | Q1           | Putting the Pieces Together: REMS Logic Model in REMS Design, Implementation, and Evaluation<br><a href="http://www.fda.gov/drugs/news-events-human-drugs/putting-pieces-together-rems-logic-model-rems-design-implementation-and-evaluation-11072024">www.fda.gov/drugs/news-events-human-drugs/putting-pieces-together-rems-logic-model-rems-design-implementation-and-evaluation-11072024</a> | 11/7/2024  | No                                                           |

|    |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |            |     |
|----|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----|
| 3  | Q1 | Optimizing the Use of Real-World Evidence in Regulatory Decision-Making for Drugs and Biological Products<br><a href="http://www.fda.gov/drugs/optimizing-use-real-world-evidence-regulatory-decision-making-drugs-and-biological-products-12122024">www.fda.gov/drugs/optimizing-use-real-world-evidence-regulatory-decision-making-drugs-and-biological-products-12122024</a>                                                                                                            | 12/12/2024 | No  |
| 4  | Q2 | BsUFA III Regulatory Science Pilot Program: Progress Update<br><a href="http://www.fda.gov/drugs/news-events-human-drugs/bsufa-iii-regulatory-science-pilot-program-progress-update-01222025">www.fda.gov/drugs/news-events-human-drugs/bsufa-iii-regulatory-science-pilot-program-progress-update-01222025</a>                                                                                                                                                                            | 1/22/2025  | No  |
| 5  | Q4 | Lessons Learned From the Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP) Program<br><a href="http://www.fda.gov/drugs/news-events-human-drugs/lessons-learned-chemistry-manufacturing-and-controls-cmc-development-and-readiness-pilot-cdrp">www.fda.gov/drugs/news-events-human-drugs/lessons-learned-chemistry-manufacturing-and-controls-cmc-development-and-readiness-pilot-cdrp</a>                                                               | 9/10/2025  | No  |
| 6  | Q4 | FDA Public Meeting: BsUFA III Regulatory Science Program Interim Public Meeting<br><a href="http://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-public-meeting-bsufa-iii-regulatory-science-program-interim-public-meeting-09182025">www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-public-meeting-bsufa-iii-regulatory-science-program-interim-public-meeting-09182025</a>                                                                      | 9/18/2025  | Yes |
| 7  | Q4 | FDA Public Workshop: Future Needs for the Development of Interchangeable Products<br><a href="http://www.fda.gov/industry/fda-public-workshop-future-needs-development-interchangeable-products-09192025">www.fda.gov/industry/fda-public-workshop-future-needs-development-interchangeable-products-09192025</a>                                                                                                                                                                          | 9/19/2025  | Yes |
| 8  | Q4 | Prescription Drug User Fee Act and Biosimilar User Fee Amendments Hiring and Retention Assessment Public Meeting<br><a href="http://www.fda.gov/drugs/news-events-human-drugs/prescription-drug-user-fee-act-and-biosimilar-user-fee-amendments-hiring-and-retention-assessment">www.fda.gov/drugs/news-events-human-drugs/prescription-drug-user-fee-act-and-biosimilar-user-fee-amendments-hiring-and-retention-assessment</a>                                                           | 9/24/2025  | Yes |
| 9  | Q4 | Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments<br><a href="http://www.federalregister.gov/documents/2025/08/21/2025-15936/financial-transparency-and-efficiency-of-the-prescription-drug-user-fee-act-biosimilar-user-fee-act">www.federalregister.gov/documents/2025/08/21/2025-15936/financial-transparency-and-efficiency-of-the-prescription-drug-user-fee-act-biosimilar-user-fee-act</a> | 9/30/2025  | Yes |
| 10 | Q4 | FDA Public Meeting: Onshoring Manufacturing of Drugs and Biological Products<br><a href="http://www.fda.gov/drugs/news-events-human-drugs/fda-public-meeting-onshoring-manufacturing-drugs-and-biological-products-09302025">www.fda.gov/drugs/news-events-human-drugs/fda-public-meeting-onshoring-manufacturing-drugs-and-biological-products-09302025</a>                                                                                                                               | 9/30/2025  | Yes |