Performance Report to Congress

Biosimilar User Fee Act

FY 2025

Executive Summary

The Biosimilar User Fee Act (BsUFA) provides funding to the Food and Drug Administration (FDA) for the review of biosimilar biological products. Following the success of the first and second authorization of BsUFA, FDA developed enhancements for the third authorization of BsUFA (BsUFA III) in consultation with regulated industry representatives, patient and consumer advocates, health care professionals, and other public stakeholders. These consultations led to the BsUFA performance goals for the fiscal year (FY) 2023 to 2027 period, detailed in the BsUFA III Commitment Letter.[1]

BsUFA provides FDA with user fee revenue to expedite the process for the review of biosimilar biological product submissions, including applications, supplements, notifications, responses, and meeting management.

Information Included in This Report

This report marks the 13th year of the BsUFA program and the third year of BsUFA III. The report presents FDA's final performance results in meeting BsUFA goals and commitments for FY 2024 and FDA's preliminary performance results for FY 2025.

Program Performance Results

FDA continues to work towards improving its performance in meeting or exceeding expectations in the implementation and completion of the performance goals established in the BsUFA III Commitment Letter. Additional information regarding corrective actions for missed goals can be found in Appendix C of the report. Key highlights for the BsUFA program include the following:

- For the FY 2024 cohort, FDA met or exceeded 27 of the 30 goals. (There were 43 goals, but only 30 had applicable submissions.)

- FDA has the potential to meet or exceed 30 of the 34 goals that apply to the FY 2025 cohort once these actions are completed. (There are 43 goals, but only 34 have applicable submissions.)

[1] Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027, available at https://www.fda.gov/media/152279/download.

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Acronym List

BPD	Biosimilar Biological Product Development
BsUFA	Biosimilar User Fee Act
BIA	Biosimilar Initial Advisory
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
ETASU	Elements to Assure Safe Use
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration
FTE	Full-Time Equivalents
FUFRA	FDA User Fee Reauthorization Act of 2022
FY	Fiscal Year (October 1 to September 30)
IND	Investigational New Drug Application
iPSP	Initial Pediatric Study Plan
OC	Office of the Commissioner
OND	Office of New Drugs
OII	Office of Inspections and Investigations
PDUFA	Prescription Drug User Fee Act
PHS Act	Public Health Service Act
REMS	Risk Evaluation and Mitigation Strategy
WCF	Working Capital Fund

Introduction

The Biosimilar User Fee Act (BsUFA) was first authorized in 2012, and was reauthorized as BsUFA II on August 18, 2017, for an additional 5 years (covering fiscal year (FY) 2018 through FY 2022) as part of the FDA Reauthorization Act of 2017. On September 30, 2022, the President signed into law the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Public Law 117-180), which contains the FDA User Fee Reauthorization Act of 2022 (FUFRA). FUFRA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to reauthorize BsUFA for an additional 5 years (i.e., FY 2023 through FY 2027), which then became BsUFA III.

BsUFA III authorizes the Food and Drug Administration (FDA or Agency) to assess and collect fees for biosimilar biological products. FDA dedicates these fees to the efficient review of submissions for biosimilar biological products (also referred to as "biosimilars") and to facilitate the development of safe and effective biosimilars for the American public.

A. Performance Results Presented in This Report

This report presents FDA's final performance results in meeting BsUFA goals and commitments for FY 2024 and FDA's preliminary performance results for FY 2025. These data represent FDA's performance on submissions received and actions taken as of September 30, 2025. Final FDA performance results for FY 2025 submissions will be presented in the FY 2026 BsUFA performance report and will include final actions for submissions still pending within the BsUFA goal date as of September 30, 2025. More detailed information on submissions and performance calculations, as well as definitions of key terms used in this report, is presented in the appendices. The following information refers to the performance presented in this report.

- The following terminology is used throughout this document:
  - *Application* means a new, original application.
  - *Supplement* means a supplement to an approved application.
  - *Resubmission* means a resubmitted application or supplement in response to a complete response.
  - *Submission* applies to all the above.
  - *Action* refers to the issuance of a complete action letter for any submission.

- Performance goal results are reported for each *fiscal year receipt cohort* (defined as submissions filed from October 1 to September 30 of the following year). In each fiscal year, FDA receives submissions that will have associated goals due in the following fiscal year. In these cases, FDA's performance will be reported in subsequent fiscal years, either after the Agency takes an action or when the goal

becomes overdue, whichever comes first.

- Filed applications and supplements include submissions that have been filed or are in pending filing status. Data do not include submissions that are unacceptable for filing because of nonpayment of user fees, have been withdrawn within 60 days of receipt, or have been refused to file. Data includes applications or supplements that were administratively split to allow the Agency to take different actions with respect to different aspects of the submission.

- Unless otherwise noted, all performance data are as of September 30, 2025.

- For resubmitted applications, the applicable performance goal is determined by the fiscal year in which the resubmission is received, rather than the year in which the original application was submitted.

- For original biosimilar product applications reviewed under the program (see the BsUFA III Commitment Letter[2] for more information about the "Program for Enhanced Review Transparency and Communication for Original 351(k) BLAs"), the BsUFA clock begins at the conclusion of the 60-day filing period. For all other submissions, the BsUFA clock begins upon FDA's receipt of the submission.

[2] Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027, available at https://www.fda.gov/media/152279/download.

Biosimilar Application and Supplement Types

- **Original Biosimilar Product Application** – A new application for licensure of a biological product under section 351(k) of the Public Health Service Act (PHS Act).
- **Resubmitted Original Biosimilar Product Application** – A complete response to an action letter for an original application addressing all identified deficiencies.
- **Original Supplement with Clinical Data** – A request for FDA to approve a change in a biosimilar product application that was approved, including a supplement requesting that FDA determine that the approved biosimilar meets the standards for interchangeability described in section 351(k)(4) of the PHS Act, that contains clinical data.[3]
- **Resubmitted Supplement with Clinical Data** – A complete response to an action letter for an original supplement with clinical data addressing all identified deficiencies.[3]
- **Manufacturing Supplement** – A request for FDA to approve a change in the manufacturing of an approved biosimilar.
- **Original Category A Supplement** – A request for FDA to approve a change in the labeling for a licensed biosimilar or interchangeable product with regards to safety information that has been updated in the reference product labeling and is applicable to one or more indications for which the biosimilar or interchangeable product is licensed.
- **Original Category B Supplement** – A request for FDA to approve an additional indication for a licensed biosimilar or interchangeable product when the submission does not include new data sets (other than analytical in vitro data obtained by use of physical, chemical and/or biological function assays, if needed to support the scientific justification for extrapolation) provided that the supplement does not request approval for a new route of administration, dosage form, dosage strength, formulation or presentation, and, if the supplement is subject to section 505B(a) of the FD&C Act, the supplement contains an up-to-date agreed initial pediatric study plan (iPSP).
- **Original Category C Supplement** – A request for FDA to approve a change seeking to remove an approved indication for a licensed biosimilar or interchangeable product.
- **Original Category D Supplement** – A request for FDA to approve an additional indication for a licensed biosimilar or interchangeable product when the submission contains new data sets or does not contain new data sets but is subject to section 505B(a) of the FD&C Act and the supplement does not contain an up-to-date agreed iPSP.
- **Original Category E Supplement** – A request for FDA to approve an additional indication for a licensed biosimilar or interchangeable product and containing efficacy data sets.
- **Original Category F Supplement** – A request for FDA to approve an initial determination of interchangeability.
- **Resubmitted Category A through Category F Supplement** – A complete response to an action letter for an original Category A through Category F supplement addressing all identified deficiencies.

Additional definitions are included in Appendix A of this report.

[3] The Original Supplement with Clinical Data and Resubmitted Supplement with Clinical Data supplement types were superseded by the Original Category A through F and Resubmitted Category A through F supplement types in BsUFA III.

BsUFA Performance Goals and Commitments

Tables 1 and 2 present the goal timelines and the percentage of submissions that FDA committed to review within those goal timelines for FY 2023 through FY 2027. Additional information on the BsUFA performance metrics and definitions for Biosimilar Biological Product Development (BPD) meeting types can be found in Appendix A.

Table 1. BsUFA Review Goals from FY 2023 to FY 2027.

BsUFA Submission Type	Goal: Act on Within	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Biosimilar Applications and Supplements						
Original Biosimilar Product Applications	10 months from 60-day filing date	90%	90%	90%	90%	90%
Resubmitted Original Biosimilar Applications	6 months	90%	90%	90%	90%	90%
Original Category A Supplements	3 months	70%	80%	90%	90%	90%
Original Category B Supplements	4 months	70%	80%	90%	90%	90%
Original Category C Supplements	4 months	70%	80%	90%	90%	90%
Original Category D Supplements	6 months	70%	80%	90%	90%	90%
Original Category E Supplements	10 months	90%	90%	90%	90%	90%
Original Category F Supplements	10 months	90%	90%	90%	90%	90%
Resubmitted Category A Supplements	3 months	70%	80%	90%	90%	90%
Resubmitted Category B Supplements	4 months	70%	80%	90%	90%	90%
Resubmitted Category C Supplements	4 months	70%	80%	90%	90%	90%
Resubmitted Category D Supplements	6 months	70%	80%	90%	90%	90%
Resubmitted Category E Supplements	6 months	90%	90%	90%	90%	90%
Resubmitted Category F Supplements	6 months	90%	90%	90%	90%	90%
Manufacturing Supplements Requiring Prior Approval	4 months	90%	90%	90%	90%	90%
Manufacturing Supplements Not Requiring Prior Approval	6 months	90%	90%	90%	90%	90%

Table 2. BsUFA Procedural and Processing Goals from FY 2023 to FY 2027.

BsUFA Procedural/Processing Type	Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Procedural Notifications						
Notification of Receipt and Planned Review Timeline for Original Category A through D Supplements	Notify within 60 days	90%	90%	90%	90%	90%
Notification of Receipt, Planned Review Timeline, and Substantive Issues Identified During the Filing Review for Category E and F Supplements	Notify within 74 days	90%	90%	90%	90%	90%
Review of Proprietary Names Submitted During BPD Phase	Review and notify of tentative acceptance or non-acceptance within 180 days	90%	90%	90%	90%	90%
Review of Proprietary Names Submitted During Application Review	Review and notify of tentative acceptance or non-acceptance within 90 days	90%	90%	90%	90%	90%
Procedural Responses						
Major Dispute Resolutions	Respond within 30 days	90%	90%	90%	90%	90%
Responses to Clinical Holds	Respond within 30 days	90%	90%	90%	90%	90%
Special Protocol Assessments	Complete and return within 45 days	90%	90%	90%	90%	90%
Human Factors Validation Protocol Submissions to INDs	Review and provide comments within 60 days	90%	90%	90%	90%	90%
Use-Related Risk Analysis Submissions	Review and respond within 60 days	--	50%	70%	90%	90%

BsUFA Procedural/Processing Type	Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Meeting Management						
Biosimilar Initial Advisory Meeting Requests	Respond within 21 days	90%	90%	90%	90%	90%
BPD Type 1 Meeting Requests	Respond within 14 days	90%	90%	90%	90%	90%
BPD Type 2a Meeting Requests	Respond within 21 days	90%	90%	90%	90%	90%
BPD Type 2b Meeting Requests	Respond within 21 days	90%	90%	90%	90%	90%
BPD Type 3 Meeting Requests	Respond within 21 days	90%	90%	90%	90%	90%
BPD Type 4 Meeting Requests	Respond within 21 days	90%	90%	90%	90%	90%
Biosimilar Initial Advisory Meetings Scheduled	Schedule within 75 days	90%	90%	90%	90%	90%
BPD Type 1 Meetings Scheduled	Schedule within 30 days	90%	90%	90%	90%	90%
BPD Type 2a Meetings Scheduled	Schedule within 60 days	50%	60%	70%	80%	90%
BPD Type 2b Meetings Scheduled	Schedule within 90 days	90%	90%	90%	90%	90%
BPD Type 3 Meetings Scheduled	Schedule within 120 days	90%	90%	90%	90%	90%
BPD Type 4 Meetings Scheduled	Schedule within 60 days	90%	90%	90%	90%	90%
Biosimilar Initial Advisory Written Response	Send within 75 days	90%	90%	90%	90%	90%
BPD Type 2a Written Response	Send within 60 days	50%	60%	70%	80%	90%
BPD Type 2b Written Response	Send within 90 days	90%	90%	90%	90%	90%
Preliminary Responses for BPD Type 2b	Issue no later than 5 days prior to meeting date	90%	90%	90%	90%	90%
Preliminary Responses for BPD Type 3	Issue no later than 5 days prior to meeting date	90%	90%	90%	90%	90%
Meeting Minutes for All Meeting Types	Issue within 30 days after meeting date	90%	90%	90%	90%	90%

FY 2024 Final BsUFA Performance Summary

FY 2024 final BsUFA goal performance results and performance details are presented in Tables 3 through 7 below. Of the 43 BsUFA goal categories, 30 applied to FY 2024 biosimilar biological product submissions. FDA met or exceeded 27 of these 30 goals. No submissions were received for 13 of the 43 BsUFA goal categories, indicated with an "N/A" in the tables below.

A. FY 2024 Final Review Goal Performance Results

The FY 2024 final BsUFA review goal performance results are presented in Table 3 below.

- The *Percent on Time* column presents the percentage of actions completed that were reviewed within the specified goal.

- The *Goal Met* column indicates submission types that met or exceeded the performance goal.

FDA met or exceeded the performance level for 8 of the 8 review goals in FY 2024. There are 16 review goals, but only 8 had submissions.

Table 3. FY 2024 Final Review Goal Performance Results.

BsUFA Submission Type	Goal: Act on Within	On Time	Performance Goal	Percent on Time	Goal Met
Biosimilar Applications and Supplements					
Original Biosimilar Product Applications	10 months from 60-day filing date	22 of 23	90%	96%	Yes
Resubmitted Original Biosimilar Applications	6 months	9 of 9	90%	100%	Yes
Original Category A Supplements	3 months	3 of 3	80%	100%	Yes
Original Category B Supplements	4 months	3 of 3	80%	100%	Yes
Original Category C Supplements	4 months	0 of 0	80%	N/A	N/A
Original Category D Supplements	6 months	4 of 5	80%	80%	Yes
Original Category E Supplements	10 months	0 of 0	90%	N/A	N/A
Original Category F Supplements	10 months	4 of 4	90%	100%	Yes
Resubmitted Category A Supplements	3 months	0 of 0	80%	N/A	N/A
Resubmitted Category B Supplements	4 months	0 of 0	80%	N/A	N/A
Resubmitted Category C Supplements	4 months	0 of 0	80%	N/A	N/A
Resubmitted Category D Supplements	6 months	0 of 0	80%	N/A	N/A
Resubmitted Category E Supplements	6 months	0 of 0	90%	N/A	N/A
Resubmitted Category F Supplements	6 months	0 of 0	90%	N/A	N/A
Manufacturing Supplements Requiring Prior Approval	4 months	62 of 67	90%	93%	Yes
Manufacturing Supplements Not Requiring Prior Approval	6 months	54 of 55	90%	98%	Yes

For submission types marked "N/A," performance goals do not apply because no submissions were received.

B. FY 2024 Final Review Goal Performance Details

Table 4 details the performance data for the FY 2024 cohort of submissions. These data include the number of submissions reviewed *On Time* (i.e., acted on by the BsUFA goal date), *Overdue* (i.e., acted on past the goal date or pending past the goal date), and the final *Percent on Time* (i.e., final performance with no actions pending within the BsUFA goal date).

The performance data presented have been updated from the preliminary performance information detailed in the FY 2024 BsUFA performance report.

Table 4. FY 2024 Final Review Goal Performance Details.

BsUFA Submission Type	Performance Goal	Timeline	Received	On Time	Overdue	Percent on Time
Biosimilar Applications and Supplements						
Original Biosimilar Product Applications	90%	10 months from 60-day filing date	23	22	1	96%
Resubmitted Original Biosimilar Applications	90%	6 months	9	9	0	100%
Original Category A Supplements	80%	3 months	3	3	0	100%
Original Category B Supplements	80%	4 months	3	3	0	100%
Original Category C Supplements	80%	4 months	0	0	0	N/A
Original Category D Supplements	80%	6 months	5	4	1	80%
Original Category E Supplements	90%	10 months	0	0	0	N/A
Original Category F Supplements	90%	10 months	4	4	0	100%
Resubmitted Category A Supplements	80%	3 months	0	0	0	N/A
Resubmitted Category B Supplements	80%	4 months	0	0	0	N/A
Resubmitted Category C Supplements	80%	4 months	0	0	0	N/A
Resubmitted Category D Supplements	80%	6 months	0	0	0	N/A
Resubmitted Category E Supplements	90%	6 months	0	0	0	N/A
Resubmitted Category F Supplements	90%	6 months	0	0	0	N/A
Manufacturing Supplements Requiring Prior Approval	90%	4 months	67	62	5	93%
Manufacturing Supplements Not Requiring Prior Approval	90%	6 months	55	54	1	98%

For submission types marked "N/A," performance goals do not apply because no submissions were received.

C. FY 2024 Final Procedural and Processing Goal Performance Results

Table 5 presents the final performance results for the FY 2024 procedural notification, procedural response, and meeting management goals.

FDA met or exceeded the performance level for 19 of the 22 procedural and processing performance goals. There are 27 procedural and processing goals, but only 22 had submissions in FY 2024.

Table 5. FY 2024 Final Procedural and Processing Goal Performance Results.

BsUFA Procedural/Processing Type	Goal	On Time	Performance Goal	Percent on Time*	Goal Met*
Procedural Notifications					
Notification of Receipt and Planned Review Timeline for Original Category A through D Supplements	Notify within 60 days	11 of 11	90%	100%	Yes
Notification of Receipt, Planned Review Timeline, and Substantive Issues Identified During the Filing Review for Category E and F Supplements	Notify within 74 days	4 of 4	90%	100%	Yes
Review of Proprietary Names Submitted During BPD Phase	Review and notify of tentative acceptance or non-acceptance within 180 days	3 of 3	90%	100%	Yes
Review of Proprietary Names Submitted During Application Review	Review and notify of tentative acceptance or non-acceptance within 90 days	40 of 40	90%	100%	Yes
Procedural Responses					
Major Dispute Resolutions	Respond within 30 days	0 of 0	90%	N/A	N/A
Responses to Clinical Holds	Respond within 30 days	0 of 0	90%	N/A	N/A
Special Protocol Assessments**	Complete and return within 45 days	2 of 2	90%	100%	Yes
Human Factors Validation Protocol Submissions to INDs	Review and provide comments within 60 days	1 of 1	90%	100%	Yes
Use-Related Risk Analysis Submissions	Review and respond within 60 days	7 of 11	50%	64%	Yes

BsUFA Procedural/Processing Type	Goal	On Time	Performance Goal	Percent on Time*	Goal Met*
Meeting Management					
Biosimilar Initial Advisory Meeting Requests†	Respond within 21 days	18 of 18	90%	100%	Yes
BPD Type 1 Meeting Requests†	Respond within 14 days	10 of 10	90%	100%	Yes
BPD Type 2a Meeting Requests†	Respond within 21 days	43 of 45	90%	96%	Yes
BPD Type 2b Meeting Requests†	Respond within 21 days	73 of 74	90%	99%	Yes
BPD Type 3 Meeting Requests†	Respond within 21 days	0 of 0	90%	N/A	N/A
BPD Type 4 Meeting Requests†	Respond within 21 days	14 of 16	90%	88%	No
Biosimilar Initial Advisory Meetings Scheduled	Schedule within 75 days	8 of 8	90%	100%	Yes
BPD Type 1 Meetings Scheduled	Schedule within 30 days	7 of 9	90%	78%	No
BPD Type 2a Meetings Scheduled	Schedule within 60 days	13 of 16	60%	81%	Yes
BPD Type 2b Meetings Scheduled	Schedule within 90 days	53 of 59	90%	90%	Yes
BPD Type 3 Meetings Scheduled	Schedule within 120 days	0 of 0	90%	N/A	N/A
BPD Type 4 Meetings Scheduled	Schedule within 60 days	13 of 16	90%	81%	No
Biosimilar Initial Advisory Written Response	Send within 75 days	9 of 10	90%	90%	Yes
BPD Type 2a Written Response	Send within 60 days	27 of 29	60%	93%	Yes
BPD Type 2b Written Response	Send within 90 days	14 of 14	90%	100%	Yes
Preliminary Response for BPD Type 2b Meetings	Issue no later than 5 days prior to meeting date	55 of 58	90%	95%	Yes
Preliminary Response for BPD Type 3 Meetings	Issue no later than 5 days prior to meeting date	0 of 0	90%	N/A	N/A
Meeting Minutes for All Meeting Types	Issue within 30 days after meeting date	67 of 72	90%	93%	Yes

* For procedural/processing types marked "N/A," performance goals do not apply because no submissions were received.
** Includes resubmitted Special Protocol Assessments, if applicable.
† Excludes meetings withdrawn prior to the meeting granted/denied response goal date.

D. FY 2024 Final Procedural and Processing Goal Performance Details

Table 6 details the performance data for the FY 2024 cohort of submissions. These data include the number of submissions reviewed *On Time* (i.e., acted on by the BsUFA goal date), *Overdue* (i.e., acted on past the goal date or pending past the goal date), and the final *Percent on Time* (i.e., final performance with no actions pending within the BsUFA goal date). Table 7 reports the number of resubmissions per original special protocol assessment as part of FDA's commitment to tracking and reporting the number of original special protocol assessments and resubmissions per original special protocol assessment.

The performance data presented have been updated from the preliminary performance information detailed in the FY 2024 BsUFA performance report.

Table 6. FY 2024 Final Procedural and Processing Goal Performance Details.

BsUFA Procedural/Processing Type	Performance Goal	Timeline	Received	On Time	Overdue	Percent on Time*
Procedural Notifications						
Notification of Receipt and Planned Review Timeline for Original Category A through D Supplements	90%	60 days	11	11	0	100%
Notification of Receipt, Planned Review Timeline, and Substantive Issues Identified During the Filing Review for Category E and F Supplements	90%	74 days	4	4	0	100%
Review of Proprietary Names Submitted During BPD Phase	90%	180 days	3	3	0	100%
Review of Proprietary Names Submitted During Application Review	90%	90 days	40	40	0	100%
Procedural Responses						
Major Dispute Resolutions	90%	30 days	0	0	0	N/A
Responses to Clinical Holds	90%	30 days	0	0	0	N/A
Special Protocol Assessments**	90%	45 days	2	2	0	100%
Human Factors Validation Protocol Submissions to INDs	90%	60 days	1	1	0	100%
Use-Related Risk Analysis Submissions	50%	60 days	11	7	4	64%

BsUFA Procedural/Processing Type	Performance Goal	Timeline	Received	On Time	Overdue	Percent on Time*
Meeting Management						
Biosimilar Initial Advisory Meeting Requests†	90%	21 days	18	18	0	100%
BPD Type 1 Meeting Requests†	90%	14 days	10	10	0	100%
BPD Type 2a Meeting Requests†	90%	21 days	45	43	2	96%
BPD Type 2b Meeting Requests†	90%	21 days	74	73	1	99%
BPD Type 3 Meeting Requests†	90%	21 days	0	0	0	N/A
BPD Type 4 Meeting Requests†	90%	21 days	16	14	2	88%
Biosimilar Initial Advisory Meetings Scheduled	90%	75 days	8	8	0	100%
BPD Type 1 Meetings Scheduled	90%	30 days	9	7	2	78%
BPD Type 2a Meetings Scheduled	60%	60 days	16	13	3	81%
BPD Type 2b Meetings Scheduled	90%	90 days	59	53	6	90%
BPD Type 3 Meetings Scheduled	90%	120 days	0	0	0	N/A
BPD Type 4 Meetings Scheduled	90%	60 days	16	13	3	81%
Biosimilar Initial Advisory Written Response	90%	75 days	10	9	1	90%
BPD Type 2a Written Response	60%	60 days	29	27	2	93%
BPD Type 2b Written Response	90%	90 days	14	14	0	100%
Preliminary Response for BPD Type 2b Meetings	90%	5 days	58	55	3	95%
Preliminary Response for BPD Type 3 Meetings	90%	5 days	0	0	0	N/A
Meeting Minutes for All Meeting Types	90%	30 days	72	67	5	93%

* For procedural/processing types marked "N/A," performance goals do not apply because no submissions were received.
** Includes resubmitted Special Protocol Assessments, if applicable.
† Excludes meetings withdrawn prior to the meeting granted/denied response goal date.

Table 7. FY 2024 Special Protocol Assessment Resubmissions.

SPAs with Resubmissions	Applications with 1 Resubmission	Applications with 2 Resubmissions	Applications with 3 Resubmissions	Applications with 4 Resubmissions	Total Resubmissions
0	0	0	0	0	0

FY 2025 Preliminary BsUFA Performance Summary

FY 2025 preliminary BsUFA performance results and performance details are presented in Tables 8 through 12.

- The *Actions Complete* column shows how much of the cohort has been acted on by presenting the number of submissions that had actions taken in FY 2025 or were overdue as of September 30, 2025, out of all submissions received. This shows the share of the cohort that has had an action taken, whether or not it met the goal.

- The *Current Performance* column presents the percentage of actions completed that were within the goal as of September 30, 2025. Actions that were pending and not yet past the goal date as of September 30, 2025, are excluded from this calculation.

- The *Highest Possible Performance* column presents the scenario where all remaining non-overdue pending submissions are reviewed on time (i.e., by the BsUFA goal date).

FDA has the potential to meet or exceed 30 of the 34 goals that apply to the FY 2025 cohort once these actions are completed. There are 43 BsUFA goal categories, but no submissions were received for 9 goals that are indicated with an "N/A" in Tables 8 through 11.

A. FY 2025 Preliminary Review Goal Performance Results

The preliminary FY 2025 review goal performance results are presented in Table 8.

- FDA is currently meeting or exceeding the performance goal for 6 of the 7 applicable goals. There are 16 review goals, but only 7 had applicable submissions to calculate a current performance. Current performance cannot be calculated for goals with only pending submissions.
- If all non-overdue pending submissions are reviewed on time, FDA will achieve the performance results presented in the *Highest Possible Performance* column. FDA has the potential to meet or exceed the performance goal for 8 of the 9 applicable review goals.

Table 8. FY 2025 Preliminary Review Goal Performance Results.

BsUFA Submission Type	Actions Complete	Goal: Act on Within	Performance Goal	Current Performance*	Highest Possible Final Performance*
Biosimilar Applications and Supplements					
Original Biosimilar Product Applications	0 of 17	10 months from 60-day filing date	90%	--†	100%
Resubmitted Original Biosimilar Applications	11 of 25	6 months	90%	100%	100%
Original Category A Supplements	8 of 11	3 months	90%	100%	100%
Original Category B Supplements	1 of 8	4 months	90%	100%	100%
Original Category C Supplements	0 of 0	4 months	90%	N/A	N/A
Original Category D Supplements	5 of 6	6 months	90%	80%	83%
Original Category E Supplements	0 of 0	10 months	90%	N/A	N/A
Original Category F Supplements	0 of 2	10 months	90%	--†	100%
Resubmitted Category A Supplements	0 of 0	3 months	90%	N/A	N/A
Resubmitted Category B Supplements	0 of 0	4 months	90%	N/A	N/A
Resubmitted Category C Supplements	0 of 0	4 months	90%	N/A	N/A
Resubmitted Category D Supplements	0 of 0	6 months	90%	N/A	N/A
Resubmitted Category E Supplements	0 of 0	6 months	90%	N/A	N/A
Resubmitted Category F Supplements	6 of 6	6 months	90%	100%	100%
Manufacturing Supplements Requiring Prior Approval	70 of 112	4 months	90%	96%	97%
Manufacturing Supplements Not Requiring Prior Approval	37 of 88	6 months	90%	97%	99%

* For submission types marked "N/A," performance goals do not apply because no submissions were received.
† Current Performance cannot be calculated as all submissions are currently pending within goal.

B. FY 2025 Preliminary Review Goal Performance Details

Table 9 provides detailed preliminary performance information for the FY 2025 cohort of submissions and includes the number of submissions filed, reviewed *On Time* (i.e., acted on by the BsUFA goal date), *Overdue* (i.e., acted on past the goal date or pending past the goal date), and *Pending within Goal* (i.e., not yet acted on but still pending within the BsUFA goal date).

Table 9. FY 2025 Preliminary Review Goal Performance Details.

BsUFA Submission Type	Performance Goal	Timeline	Filed	On Time	Overdue	Pending within Goal	Current Performance*	Highest Possible Performance*
Biosimilar Applications and Supplements								
Original Biosimilar Product Applications	90%	10 months from 60-day filing date	17	0	0	17	--†	100%
Resubmitted Original Biosimilar Applications	90%	6 months	25	11	0	14	100%	100%
Original Category A Supplements	90%	3 months	11	8	0	3	100%	100%
Original Category B Supplements	90%	4 months	8	1	0	7	100%	100%
Original Category C Supplements	90%	4 months	0	0	0	0	N/A	N/A
Original Category D Supplements	90%	6 months	6	4	1	1	80%	83%
Original Category E Supplements	90%	10 months	0	0	0	0	N/A	N/A
Original Category F Supplements	90%	10 months	2	0	0	2	--†	100%
Resubmitted Category A Supplements	90%	3 months	0	0	0	0	N/A	N/A
Resubmitted Category B Supplements	90%	4 months	0	0	0	0	N/A	N/A
Resubmitted Category C Supplements	90%	4 months	0	0	0	0	N/A	N/A
Resubmitted Category D Supplements	90%	6 months	0	0	0	0	N/A	N/A
Resubmitted Category E Supplements	90%	6 months	0	0	0	0	N/A	N/A
Resubmitted Category F Supplements	90%	6 months	6	6	0	0	100%	100%
Manufacturing Supplements Requiring Prior Approval	90%	4 months	112	67	3	42	96%	97%
Manufacturing Supplements Not Requiring Prior Approval	90%	6 months	88	36	1	51	97%	99%

* For submission types marked "N/A," performance goals do not apply because no submissions were received.
† Current Percent on Time cannot be calculated as all submissions are currently pending within goal.

C. FY 2025 Preliminary Procedural and Processing Goal Performance Results

Table 10 presents the preliminary performance results for the FY 2025 procedural notification, procedural response, and meeting management goals.

- FDA is currently meeting or exceeding the performance goal for 21 of the 24 applicable goals. There are 27 procedural and processing goals, but only 24 had applicable submissions to calculate a current performance. Current performance cannot be calculated for goals with only pending submissions.

- If all non-overdue pending submissions are reviewed on time, FDA will achieve the performance results presented in the *Highest Possible Performance* column. FDA has the potential to meet or exceed the performance goal for 22 of the 25 applicable procedural and processing goals. There are 27 procedural and processing goals, but only 25 had applicable submissions.

Table 10. FY 2025 Preliminary Procedural and Processing Goal Performance Results.

BsUFA Procedural/Processing Type	Actions Complete	Goal	Performance Goal	Current Performance*	Highest Possible Performance*
Procedural Notifications					
Notification of Receipt and Planned Review Timeline for Original Category A through D Supplements	24 of 25	Notify within 60 days	90%	96%	96%
Notification of Receipt, Planned Review Timeline, and Substantive Issues Identified During the Filing Review for Category E and F Supplements	0 of 2	Notify within 74 days	90%	--†	100%
Review of Proprietary Names Submitted During BPD Phase	6 of 8	Review and notify of tentative acceptance or non-acceptance within 180 days	90%	100%	100%
Review of Proprietary Names Submitted During Application Review	33 of 39	Review and notify of tentative acceptance or non-acceptance within 90 days	90%	97%	97%
Procedural Responses					
Major Dispute Resolutions	0 of 0	Respond within 30 days	90%	N/A	N/A
Responses to Clinical Holds	1 of 1	Respond within 30 days	90%	100%	100%
Special Protocol Assessments**	0 of 0	Complete and return within 45 days	90%	N/A	N/A
Human Factors Validation Protocol Submissions to INDs	10 of 10	Review and provide comments within 60 days	90%	90%	90%
Use-Related Risk Analysis Submissions	20 of 23	Review and respond within 60 days	70%	85%	87%

BsUFA Procedural/Processing Type	Actions Complete	Goal	Performance Goal	Current Performance*	Highest Possible Performance*
Meeting Management					
Biosimilar Initial Advisory Meeting Requests‡	28 of 28	Respond within 21 days	90%	96%	96%
BPD Type 1 Meeting Requests‡§	9 of 13	Respond within 14 days	90%	100%	100%
BPD Type 2a Meeting Requests‡	51 of 53	Respond within 21 days	90%	90%	91%
BPD Type 2b Meeting Requests‡	75 of 76	Respond within 21 days	90%	96%	96%
BPD Type 3 Meeting Requests‡	3 of 3	Respond within 21 days	90%	100%	100%
BPD Type 4 Meeting Requests‡	13 of 13	Respond within 21 days	90%	100%	100%
Biosimilar Initial Advisory Meetings Scheduled	21 of 21	Schedule within 75 days	90%	86%	86%
BPD Type 1 Meetings Scheduled§	9 of 13	Schedule within 30 days	90%	78%	85%
BPD Type 2a Meetings Scheduled	24 of 26	Schedule within 60 days	70%	96%	96%
BPD Type 2b Meetings Scheduled	53 of 54	Schedule within 90 days	90%	92%	93%
BPD Type 3 Meetings Scheduled	3 of 3	Schedule within 120 days	90%	100%	100%
BPD Type 4 Meetings Scheduled	13 of 13	Schedule within 60 days	90%	92%	92%
Biosimilar Initial Advisory Written Response	3 of 7	Send within 75 days	90%	100%	100%
BPD Type 2a Written Response	25 of 26	Send within 60 days	70%	96%	96%
BPD Type 2b Written Response	12 of 19	Send within 90 days	90%	83%	89%
Preliminary Response for BPD Type 2b Meetings	38 of 53	Issue no later than 5 days prior to meeting date	90%	95%	96%
Preliminary Response for BPD Type 3 Meetings	1 of 3	Issue no later than 5 days prior to meeting date	90%	100%	100%
Meeting Minutes for All Meeting Types	46 of 79	Issue within 30 days after meeting date	90%	96%	97%

* For procedural / processing types marked "N/A," performance goals do not apply because no submissions were received.
** Includes resubmitted Special Protocol Assessments, if applicable.
† Current Performance cannot be calculated as all submissions are currently pending within goal.
‡ Excludes meetings withdrawn prior to the meeting granted/denied response goal date.
§ Some meeting requests and the subsequent scheduling of meetings are for requests in which the type cannot be initially determined. There were 4 undesignated meetings counted as BPD Type 1 meeting requests and BPD Type 1 meetings scheduled in the table above. Performance in all categories will change once designations are made for these requests and will be updated in the FY 2026 BsUFA Performance Report.

D. FY 2025 Preliminary Procedural and Processing Goal Performance Details

Table 11 provides detailed preliminary performance information for FY 2025 cohort submissions, including the number of submissions *Received*, reviewed *On Time* (i.e., acted on by the BsUFA goal date), and *Overdue* (i.e., acted on past the goal date or pending past the goal date). The number of submissions not yet acted on but still pending within the BsUFA goal date (*Pending Within Goal*) is also provided, along with the highest possible percent of reviews that may be completed on time (*Highest Possible Performance*). Table 12 reports the number of resubmissions per original special protocol assessment as part of FDA's commitment to tracking and reporting the number of original special protocol assessments and resubmissions per original special protocol assessment.

Table 11. FY 2025 Preliminary Procedural and Processing Goal Performance Details.

BsUFA Procedural/ Processing Type	Performance Goal	Timeline	Received	On Time	Overdue	Pending within Goal	Current Performance*	Highest Possible Performance*
Procedural Notifications								
Notification of Receipt and Planned Review Timeline for Original Category A through D Supplements	90%	60 days	25	23	1	1	96%	96%
Notification of Receipt, Planned Review Timeline, and Substantive Issues Identified During the Filing Review for Category E and F Supplements	90%	74 days	2	0	0	2	--†	100%
Review of Proprietary Names Submitted During BPD Phase	90%	180 days	8	6	0	2	100%	100%
Review of Proprietary Names Submitted During Application Review	90%	90 days	39	32	1	6	97%	97%
Procedural Responses								
Major Dispute Resolutions	90%	30 days	0	0	0	0	N/A	N/A
Responses to Clinical Holds	90%	30 days	1	1	0	0	100%	100%
Special Protocol Assessments**	90%	45 days	0	0	0	0	N/A	N/A
Human Factors Validation Protocol Submissions to INDs	90%	60 days	10	9	1	0	90%	90%
Use-Related Risk Analysis Submissions	70%	60 days	23	17	3	3	85%	87%

BsUFA Procedural/ Processing Type	Performance Goal	Timeline	Received	On Time	Overdue	Pending within Goal	Current Performance*	Highest Possible Performance*
Meeting Management								
Biosimilar Initial Advisory Meeting Requests‡	90%	21 days	28	27	1	0	96%	96%
BPD Type 1 Meeting Requests‡§	90%	14 days	13	9	0	4	100%	100%
BPD Type 2a Meeting Requests‡	90%	21 days	53	46	5	2	90%	91%
BPD Type 2b Meeting Requests‡	90%	21 days	76	72	3	1	96%	96%
BPD Type 3 Meeting Requests‡	90%	21 days	3	3	0	0	100%	100%
BPD Type 4 Meeting Requests‡	90%	21 days	13	13	0	0	100%	100%
Biosimilar Initial Advisory Meetings Scheduled	90%	75 days	21	18	3	0	86%	86%
BPD Type 1 Meetings Scheduled§	90%	30 days	13	7	2	4	78%	85%
BPD Type 2a Meetings Scheduled	70%	60 days	26	23	1	2	96%	96%
BPD Type 2b Meetings Scheduled	90%	90 days	54	49	4	1	92%	93%
BPD Type 3 Meetings Scheduled	90%	120 days	3	3	0	0	100%	100%
BPD Type 4 Meetings Scheduled	90%	60 days	13	12	1	0	92%	92%
Biosimilar Initial Advisory Written Response	90%	75 days	7	3	0	4	100%	100%
BPD Type 2a Written Response	70%	60 days	26	24	1	1	96%	96%
BPD Type 2b Written Response	90%	90 days	19	10	2	7	83%	89%
Preliminary Response for BPD Type 2b Meetings	90%	5 days	53	36	2	15	95%	96%
Preliminary Response for BPD Type 3 Meetings	90%	5 days	3	1	0	2	100%	100%
Meeting Minutes for All Meeting Types	90%	30 days	79	44	2	33	96%	97%

* For procedural / processing types marked "N/A," performance goals do not apply because no submissions were received.
** Includes resubmitted Special Protocol Assessments, if applicable.
† Current Performance cannot be calculated as all submissions are currently pending within goal.
‡ Excludes meetings withdrawn prior to the meeting granted/denied response goal date.
§ Some meeting requests and the subsequent scheduling of meetings are for requests in which the type cannot be initially determined. There were 4 undesignated meetings counted as BPD Type 1 meeting requests and BPD Type 1 meetings scheduled in the table above. Performance in all categories will change once designations are made for these requests and will be updated in the FY 2026 BsUFA Performance Report.

Table 12. FY 2025 Special Protocol Assessment Resubmissions.

SPAs with Resubmissions	Applications with 1 Resubmission	Applications with 2 Resubmissions	Applications with 3 Resubmissions	Applications with 4 Resubmissions	Total Resubmissions
0	0	0	0	0	0

BsUFA Workload

Tables 13 and 14 present the workload numbers from FY 2021 to FY 2025.

Table 13. Review Workload from FY 2021 to FY 2025.

BsUFA Workload	FY 2021	FY 2022	FY 2023	FY 2024*	FY 2025
Biosimiliar Applications and Supplements					
Original Biosimilar Product Applications	10	11	26	23	17
Resubmitted Original Biosimilar Applications	5	7	12	9	25
Original Supplements with Clinical Data	10	16	--	--	--
Resubmitted Supplements with Clinical Data	1	0	--	--	--
Original Category A Supplements	--	--	5	3	11
Original Category B Supplements	--	--	1	3	8
Original Category C Supplements	--	--	0	0	0
Original Category D Supplements	--	--	11	5	6
Original Category E Supplements	--	--	0	0	0
Original Category F Supplements	--	--	6	4	2
Resubmitted Category A Supplements	--	--	0	0	0
Resubmitted Category B Supplements	--	--	0	0	0
Resubmitted Category C Supplements	--	--	0	0	0
Resubmitted Category D Supplements	--	--	0	0	0
Resubmitted Category E Supplements	--	--	0	0	0
Resubmitted Category F Supplements	--	--	0	0	6
Manufacturing Supplements Requiring Prior Approval	50	40	47	67	112
Manufacturing Supplements Not Requiring Prior Approval	40	32	41	55	88

For submission types marked "--," workload is not applicable as the goal was not reported during that fiscal year.
* FY 2024 numbers were changed to reflect updates to the data presented in the FY 2024 BsUFA Performance Report.

Table 14. Procedural and Processing Workload from FY 2021 to FY 2025.

BsUFA Workload	FY 2021	FY 2022	FY 2023	FY 2024*	FY 2025
Procedural Notifications					
Notification of Issues Identified During Filing Review for Supplements with Clinical Data	7	8	--	--	--
Notification of Planned Review Timeline for Supplements with Clinical Data	7	8	--	--	--
Notification of Receipt and Planned Review Timeline for Original Category A through D Supplements	--	--	19	11	25
Notification of Receipt, Planned Review Timeline, and Substantive Issues Identified During the Filing Review for Category E and F Supplements	--	--	6	4	2
Review of Proprietary Names Submitted During BPD Phase	8	12	18	3	8
Review of Proprietary Names Submitted During Application Review	15	24	40	40	39
Procedural Responses					
Human Factors Validation Protocol Submissions to INDs	--	--	6	1	10
Major Dispute Resolutions	0	0	0	0	0
Responses to Clinical Holds	2	0	0	0	1
Special Protocol Assessments**	1	3	4	2	0
Use-Related Risk Analysis Submissions	--	--	--	11	23

BsUFA Workload	FY 2021	FY 2022	FY 2023	FY 2024*	FY 2025
Meeting Management					
Biosimilar Initial Advisory Meeting Requests†	6	9	14	18	28
BPD Type 1 Meeting Requests†‡	4	14	8	10	13
BPD Type 2 Meeting Requests†§	90	97	--	--	--
BPD Type 2a Meeting Requests†	--	--	36	45	53
BPD Type 2b Meeting Requests†	--	--	52	74	76
BPD Type 3 Meeting Requests†	7	2	1	0	3
BPD Type 4 Meeting Requests†	10	13	24	16	13
Biosimilar Initial Advisory Meetings Scheduled	3	4	11	8	21
BPD Type 1 Meetings Scheduled‡	4	14	5	9	13
BPD Type 2 Meetings Scheduled§	64	77	--	--	--
BPD Type 2a Meetings Scheduled	--	--	19	16	26
BPD Type 2b Meetings Scheduled	--	--	42	59	54
BPD Type 3 Meetings Scheduled	6	2	1	0	3
BPD Type 4 Meetings Scheduled	10	13	24	16	13
Biosimilar Initial Advisory Written Response	2	3	2	10	7
BPD Type 2 Written Responses§	23	14	--	--	--
BPD Type 2a Written Response	--	--	16	29	26
BPD Type 2b Written Response	--	--	9	14	19
Preliminary Response for BPD Type 2 Meetings	64	76	--	--	--
Preliminary Response for BPD Type 2b Meetings	--	--	40	58	53
Preliminary Response for BPD Type 3 Meetings	6	2	1	0	3
Meeting Minutes for All Meeting Types	68	76	68	72	79

For submission types marked "--," workload is not applicable as the goal was not reported during that fiscal year.
* FY 2024 numbers were changed to reflect updates to the data presented in the FY 2024 BsUFA Performance Report.
* * Includes resubmitted Special Protocol Assessments, if applicable.
† Excludes meeting submissions that are unacceptable for filing because of either a nonpayment of user fees or a withdrawal of a meetings request prior to the meeting's granted/denied response goal date.
‡ Some meeting requests and the subsequent scheduling of meetings are for requests in which the type cannot be initially determined. There were four undesignated meetings in FY 2025 counted as BPD Type 1 meeting requests and BPD Type 1 meetings scheduled in the table above. Performance in all categories will change once designations are made for these requests and will be updated in the FY 2026 BsUFA Performance Report.
§ Two new categories of BPD Type 2 (i.e., BPD Type 2a and BPD Type 2b) were created under BsUFA III. Therefore, when doing a trend analysis comparing BPD Type 2 data from the most recent fiscal year to the previous fiscal years, it is important to include both BPD Type 2a and BPD Type 2b meeting categories.

Additional Reporting Requirements

Section 715(b) of the FD&C Act requires that, each fiscal year, FDA report the following:

- The number of applications for approval filed under section 351(k) of the PHS Act;

- The percentage of applications described in subparagraph (A) of section 408 (i.e., the above bullet) that were approved by the Secretary of Health and Human Services; and,

- An explanation of how FDA is managing the biosimilar biological product review program to ensure that the user fees collected under part 2 of subchapter C of chapter VII of the FD&C Act (21 U.S.C. 379g et seq.) are not used to review an application under section 351(k) of the PHS Act.

As of September 30, 2025, 131 351(k) applications were accepted for filing by FDA.

As of September 30, 2025, 67 percent of the 351(k) applications that have been filed by FDA have been approved. This percentage captures both first cycle approvals and multiple cycle approvals.

In reference to the third bullet above, FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) are managing the biosimilar review program to ensure user fees collected under the Prescription Drug User Fee Act, the Medical Device User Fee Amendments, or the Generic Drug User Fee Amendments are not used to review applications under section 351(k) of the PHS Act. Both Centers track employee workload activities through time reporting to ensure that labor costs related to the process for the review of biosimilar biological product applications (versus those for the review of other human drugs, medical devices, or other activities) are recorded as BsUFA work and funded from appropriate accounts.

Section 744I(a)(2) of the FD&C Act requires that FDA report on the following items for each fiscal year:

- Information on all previous cohorts for which the Secretary has not given a complete response on all biosimilar biological product applications and supplements in the cohort;

- The number of original biosimilar biological product applications filed per fiscal year, and the number of approvals issued by the Agency for such applications; and,

- The number of resubmitted original biosimilar biological product applications filed per fiscal year and the number of approval letters issued by the Agency for such applications.

There are no biosimilar product applications that have not received an action from the FY 2024 cohort.

Table 15. Original Biosimilar Product Applications and Resubmitted Original Biosimilar Product Applications Filed* and Approvals to Such Applications.

Application Type	FY 2025 (Filed* / Approved as of 9/30/2025)		
Original Biosimilar Product Applications	17	/	0
Resubmitted Original Biosimilar Applications	25	/	8

* For this reporting table, "Filed" counts include applications that have been filed, are in pending filing status, or have been accepted as a resubmission. Data do not reflect applications that are unacceptable for filing because of nonpayment of user fees, have been withdrawn within 60 days of receipt, or have been refused to file.

Rationale for BsUFA Program Changes

Section 744I(a)(4) of the FD&C Act requires the following annual BsUFA performance reporting:

(A) data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 4001(b) of the Biosimilar User Fee Amendments of 2022, the number of remaining vacancies, the number of full-time equivalents (FTEs) funded by fees collected pursuant to section 744H, and the number of FTEs funded by budget authority at the Food and Drug Administration by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Inspections and Investigations (OII)[4], and the Office of the Commissioner;

(B) data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of biosimilar biological product applications, including identifying:

(i) drivers of such changes; and,
(ii) changes in the average total cost per full-time equivalent in the biosimilar biological product review program.

(C) for each of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Inspections and Investigations (OII), and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required; and,

(D) data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of each type of biosimilar biological product application.

The information below fulfills these reporting requirements.

[4] In FY 2025 the Office of Regulatory Affairs became the Office of Inspections and Investigations (OII).

A. Changes in the number of individuals hired as agreed upon in the BsUFA III Commitment Letter, the number of remaining vacancies, the number of FTEs funded by fees collected and the number of FTEs funded by budget authority at FDA.

This section addresses the requirement to provide data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 4001(b) of the Biosimilar User Fee Amendments of 2022, the remaining vacancies, the number of FTEs funded by fees collected pursuant to section 744H, and the number of FTEs funded by budget authority at FDA by each division within CDER, CBER, OII, and OC.

1. Changes in the Number of Individuals Hired as Agreed Upon in the BsUFA III Commitment Letter and Remaining Vacancies

The BsUFA III Commitment Letter states that FDA will target hiring zero individuals in FY 2025 to enhance the biosimilar biological product review program. The data in Table 16 show the changes from FY 2024 to FY 2025 in the number of individuals hired as agreed upon in the BsUFA III Commitment Letter.

Table 16. Change in the Number of Individuals Hired as Agreed Upon in the BsUFA III Commitment Letter and Remaining Vacancies.

Center	Number Hired in FY 2024	Number Hired in FY 2025	Change in Number Hired	Remaining Vacancies in FY 2024	Remaining Vacancies in FY 2025	Change in Number of Remaining Vacancies
CDER	6	0	-6	2	2	0
CBER	N/A	N/A	N/A	N/A	N/A	N/A
OC	N/A	N/A	N/A	N/A	N/A	N/A
OII	N/A	N/A	N/A	N/A	N/A	N/A
Total	6	0	-6	2	2	0

* The BsUFA III Commitment Letter describes only hiring commitments for CDER.

2. Changes in the Number of FTEs Funded by Fees Collected and the Number of FTEs Funded by Budget Authority by Division

The data in Table 17 show the number of FTEs funded by fees collected and the number of FTEs funded by budget authority in FY 2025 by each division within CDER, CBER, OII, and OC. This table reflects the number of FTEs by funding source for the BsUFA III program. For this table, "budget authority" refers to FDA's non-user fee annual appropriations. To address the requirement that information on the number of FTEs funded by budget authority and fees be presented "by each division," the information in this table is broken down to the office level for the Centers, OII, and OC. FDA uses a 2,080-hour workload to equate to one FTE, and this calculation is reflected in the table below. The number of FTEs funded by budget authority and fees for FY 2025 are those FTEs as of September 30, 2025.

Table 17. Changes in the Number of FTEs Funded by Budget Authority and the Number of FTEs Funded by Fees.

Center and Office	Number of FTEs Funded by Budget Authority*		Change in Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees		Change in the Number of FTEs Funded by Fees
	FY 2024	FY 2025		FY 2024	FY 2025	
CDER						
Office of Communications	1.94	2.01	0.07	1.65	1.01	-0.64
Office of Compliance	0.83	0.77	-0.06	1.34	1.39	0.05
Office of the Center Director	0.69	0.51	-0.18	0.60	0.73	0.13
Office of Executive Programs	1.46	0.97	-0.49	2.11	1.79	-0.32
Office of Generic Drugs	0.15	0.00	-0.15	0.00	0.00	0.00
Office of Medical Policy	0.57	0.85	0.28	0.00	0.22	0.22
Office of Management	0.00	2.08	2.08	9.24	6.70	-2.54
Office of New Drugs	16.87	8.72	-8.15	43.66	49.36	5.70
Office of Pharmaceutical Quality	30.53	22.99	-7.54	49.54	47.94	-1.60
Office of Regulatory Policy	1.36	2.46	1.10	1.30	1.66	0.36
Office of Surveillance and Epidemiology	5.28	5.27	-0.01	7.38	8.42	1.04
Office of Strategic Programs	1.53	3.72	2.19	2.14	2.63	0.49
Office of Translational Sciences	13.02	11.25	-1.77	18.68	17.74	-0.94
Other Offices	0.26	0.00	-0.26	0.00	0.00	0.00
Working Capital Fund	3.86	3.67	-0.19	7.19	9.87	2.68

Center and Office	Number of FTEs Funded by Budget Authority*		Change in Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees		Change in the Number of FTEs Funded by Fees
	FY 2024	FY 2025		FY 2024	FY 2025	
CBER						
Office of Biostatistics and Pharmacovigilance	0.05	0.07	0.02	0.00	0.00	0.00
Office of Blood Research and Review	0.00	0.00	0.00	0.00	0.00	0.00
Office of Compliance and Biologics Quality	0.01	0.00	-0.01	0.00	0.00	0.00
Office of Therapeutic Products	0.18	0.08	-0.10	0.00	0.00	0.00
Office of Vaccines Research and Review	0.00	0.06	0.06	0.00	0.00	0.00
Office of Communication Outreach and Development	0.01	0.01	0.00	0.00	0.00	0.00
Office of the Center Director	0.06	0.01	-0.05	0.00	0.00	0.00
Office of Regulatory Operations	0.05	0.03	-0.02	0.00	0.00	0.00
Office of Management	0.06	0.03	-0.03	0.00	0.00	0.00
Office of Information Management and Technology	0.00	0.00	0.00	0.00	0.00	0.00
Working Capital Fund	0.02	0.01	-0.01	0.00	0.00	0.00
OC						
Office of the Chief Counsel	4.21	6.16	1.95	1.66	0.67	-0.99
Office of Clinical Policy and Programs	0.00	0.00	0.00	0.00	0.00	0.00
Office of Enterprise Management Services	0.00	0.00	0.00	0.00	0.00	0.00
Office of Operations	2.15	1.68	-0.47	0.85	0.18	-0.66
Office of Policy, Legislation, and International Affairs	2.60	7.06	4.46	1.04	0.76	-0.27
Working Capital Fund	0.89	1.08	0.19	0.70	0.16	-0.54
OII						
Office of Biological Products O..	0.00	0.00	0.00	7.04	5.33	-1.71
Working Capital Fund	0.47	0.38	0.09	0.54	0.44	-0.10

* This table includes BsUFA program FTEs calculated through Working Capital Fund (WCF) assessments for certain centrally administered services provided to CDER, CBER, OC, and OII. Because many employees under OC and WCF do not report time, an average cost per OC and WCF FTE was applied to derive the number of BsUFA program FTEs funded by budget authority.

B. Changes in the Average Total Cost Per FTE in the Biosimilar Biological Product Review Program

Section 744I(a)(4) of the FD&C Act requires FDA to provide data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of biosimilar biological product applications, including identifying drivers of such changes and changes in the average total cost per FTE in the biosimilar biological product review program. Accordingly, Table 18 provides data for the BsUFA fee revenue amounts and process costs for FY 2024 and FY 2025, as well as data for the changes in these amounts from FY 2024 to FY 2025. Relevant information about the data provided is as follows:

- The fee revenue amounts represent FDA's net collection of biosimilar biological product user fees.

- The review process costs represent FDA's total expenditure on the BsUFA program.

- Numbers are provided for both the most recent fiscal year (FY 2025) and prior fiscal year (FY 2024).

The process for setting the annual target revenue is set forth in the statute. For FY 2025, the base revenue amount is the target revenue amount from FY 2024 excluding any operating reserve adjustment, which was $51,058,023. The FY 2025 base revenue amount was adjusted for inflation, strategic hiring, and capacity planning. The target revenue amount of $56,012,000 (rounded to the nearest thousand) was set for FY 2025. In FY 2025, FDA had net collections of $58 million in BsUFA fees, spent $51 million in user fees for the BsUFA program, and carried forward a cumulative balance of $29 million for future fiscal years. The significant increase in net collections in FY 2025 was due to the operating reserve adjustment made in FY 2024, which resulted in lower-than-normal revenue in that year. Detailed financial information for the BsUFA user fee program can be found in the FY 2025 BsUFA financial report.

In FY 2025, BsUFA obligations decreased approximately $5 million from FY 2024. Fee-funded payroll increased slightly, while fee-funded operating obligations decreased by about $8 million from the prior year. In FY 2025, total rent-related obligations of BsUFA fees increased slightly from FY 2024.

Table 18. Changes in the Average Total Cost Per FTE in the Biosimilar Biological Product Review Program.

Revenue/Cost	FY 2024	FY 2025	Change from FY 2024 to FY 2025
Fee Revenue Amounts (Net Collections)	$34,375,378	$57,838,759	68%
Process Cost (Cost of Activities)	$91,066,972	$84,866,379	-7%
Average Total Cost Per FTE	$225,301	$233,309	4%

C. Number of Employees for Whom Time Reporting Is Required

Section 744I(a)(4) of the FD&C Act requires FDA to provide the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required in CDER, CBER, OII, and OC. Accordingly, Table 19 provides the number of employees within CDER, CBER, OII, and OC, as of September 30, 2025, who are required to report their time and those who are not required to report their time.

These data reflect time reporting across all employees in each entity, rather than only those engaged in BsUFA program activities.

Table 19. Time Reporting Requirement for FY 2025.

Center	FTEs for Which Time Reporting is Required	FTEs for Which Time Reporting is Not Required
CBER	1,149	0
CDER	4,951	0
OC	61	2,343
OII	2,901	0
Total	9,062	2,343

D. Changes in the Average FTE Hours Required to Complete Review of Each Type of Biosimilar Biological Product Application

Table 20 addresses Section 744I(a)(4) of the FD&C Act, which requires that FDA provide data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of each type of biosimilar biological product application.

Table 20. Average FTE Hours Required to Complete Review of Biosimilar Biological Product Applications.

Application Type	Average FTE Hours Required to Complete Application Reviews FY 2024	Average FTE Hours Required to Complete Application Reviews FY 2025	Change from FY 2024 to FY 2025
Original Biosimilar Product Applications	4,111	4,214	103
Total	4,111	4,214	103

To calculate the average hours required to complete the review of original biosimilar product applications, FDA compared the 3-year average (i.e., the sum of hours reported divided by the sum of applications submitted in a given 3-year period) ending in FY 2024 to the 3-year average ending in FY 2025. As application review activities span multiple fiscal years, this method provides an interpretable benchmark for any shifts in average hours required to complete application reviews over time.

Appendix A: Definitions of Key Terms

i. The phrase *review and act on* means the issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

ii. Goal Date Extensions

A. Major Amendments

i. A major amendment to an original application, supplement with clinical data, or resubmission of any of these applications, submitted at any time during the review cycle, may extend the goal date by 3 months.

ii. A major amendment may include, for example, a major new clinical study report, major re-analysis of previously submitted study(ies), submission of a Risk Evaluation and Mitigation Strategy (REMS) with Elements to Assure Safe Use (ETASU) not included in the original application, or a significant amendment to a previously submitted REMS with ETASU. Generally, changes to REMS that do not include ETASU and minor changes to REMS with ETASU will not be considered major amendments.

iii. A major amendment to a manufacturing supplement submitted at any time during the review cycle may extend the goal date by 2 months.

iv. Only one extension can be given per review cycle.

v. Consistent with the underlying principles articulated in the *Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications* draft guidance,[2] FDA's decision to extend the review clock should, except in rare circumstances, be limited to occasions where review of the new information could address outstanding deficiencies in the application and lead to approval in the current review cycle.

B. Inspections of Facilities Not Adequately Identified in an Original Application or Supplement

[2] http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm079748.pdf. This draft guidance, when finalized, will represent the current thinking of FDA on this topic.

i. All original applications and supplements are expected to include a comprehensive and readily located list of all manufacturing facilities included or referenced in the application or supplement. This list provides FDA with information needed to schedule inspections of manufacturing facilities that may be necessary before approval of the original application or supplement.

ii. If, during FDA's review of an original application or supplement, the Agency identifies a manufacturing facility that was not included in the comprehensive and readily located list, the goal date may be extended.

    1. If FDA identifies the need to inspect a manufacturing facility that is not included as part of the comprehensive and readily located list in an original application or supplement with clinical data, the goal date may be extended by 3 months.

    2. If FDA identifies the need to inspect a manufacturing facility that is not included as part of the comprehensive and readily located list in a manufacturing supplement, the goal date may be extended by 2 months.

iii. A resubmitted original application is a complete response to an action letter addressing all identified deficiencies.

iv. A BIA Meeting is an initial assessment limited to a general discussion regarding whether licensure under section 351(k) of the PHS Act may be feasible for a particular product, and, if so, general advice on the expected content of the development program. This meeting does not include any meeting that involves substantive review of summary data or full study reports.

v. A BPD Type 1 Meeting is a meeting that is necessary for an otherwise stalled drug development program to proceed (e.g., meeting to discuss clinical holds, dispute resolution meeting), a special protocol assessment meeting, or a meeting to address an important safety issue.

vi. A BPD Type 2 Meeting is a meeting to discuss a specific issue (e.g., proposed study design or endpoints) or questions where FDA will provide targeted advice regarding an ongoing biosimilar biological product development program. This meeting may include substantive review of summary data but does not include review of full study

reports.[3]

vii. A BPD Type 2a Meeting is a meeting focused on a narrow set of issues (e.g., often one, but not more than two issues and associated questions), requiring input from no more than 3 disciplines or review divisions. In order to request a Type 2a meeting, sponsors must first have had a BIA or other BPD meeting with the Agency.

viii. A BPD Type 2b Meeting is a meeting to discuss a specific issue (e.g., proposed study design or endpoints) or questions where FDA will provide advice regarding an ongoing biosimilar biological product development program. This meeting may include substantive review of summary data but does not include review of full study reports.

ix. A BPD Type 3 Meeting is an in-depth data review and advice meeting regarding an ongoing biosimilar biological product development program. This meeting includes substantive review of full study reports, FDA advice regarding the similarity between the proposed biosimilar biological product and the reference product, and FDA advice regarding additional studies, including design and analysis.

x. A BPD Type 4 Meeting is a pre-submission meeting to discuss the format and content of a complete application for an original biosimilar biological product application under the program or supplement submitted under 351(k) of the PHS Act. The purpose of this meeting is to discuss the format and content of the planned submission and other items, including identification of those studies that the sponsor is relying on to support a demonstration of biosimilarity or interchangeability, discussion of any potential review issues identified based on the information provided, identification of the status of ongoing or needed studies to adequately address the Pediatric Research Equity Act, acquainting FDA reviewers with the general information to be submitted in the marketing application (including technical information), and discussion of the best approach to the presentation and formatting of data in the marketing application.

xi. A Use-Related Risk Analysis (URRA) is employed by sponsors to identify the need for risk mitigation strategies and to design a human factors (HF) validation study. Based on a URRA, a sponsor may propose that an HF validation study is not needed to be submitted to support the safe and effective use of a biosimilar biologic-device

[3] Two new categories of BPD Type 2 (i.e., BPD Type 2a and BPD Type 2b) were created under BsUFA III and replace the BPD Type 2 Meeting.

combination product.

xii. Human factors (HF) studies are conducted to evaluate the user interface of a biosimilar biologic-device combination product to eliminate or mitigate use-related hazards that may affect the safe and effective use of the combination product.

xiii. Special Protocol Assessments: Upon specific request by a sponsor, FDA will evaluate certain protocols and issues to assess whether the design is adequate to meet the scientific and regulatory requirements identified by the sponsor.

For additional information on performance goals, refer to the BsUFA III Commitment Letter.[4]

[4] Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027, available at https://www.fda.gov/media/152279/download.

Appendix B: Analysis of Use of Funds

A. Aggregate Filings and Approvals of Original Biosimilar Applications and Category A – F Supplements

Table B-1 addresses section 744I(a)(5)(A) of the FD&C Act, which requires FDA to include an analysis of the difference between the aggregate number of biosimilar biological product applications and supplements filed and the aggregate number of approvals, accounting for (1) such applications filed during one fiscal year for which a decision is not scheduled to be made until the following fiscal year and (2) the aggregate number of applications for each fiscal year that did not meet the goals identified by the letters described in section 4001(b) of the Biosimilar User Fee Amendments of 2022 for the applicable fiscal year.

Approval data represent all approvals of biosimilar biological product applications and supplements with clinical data that occurred during FY 2025, regardless of when the application was received. Filing data represent filings of biosimilar biological product applications and Category A through F supplements that occurred during FY 2025, including those filings for which a decision was not scheduled to be made until the following fiscal year. Data are presented by the type of application, performance goal, and whether the approval occurred on time or was overdue on the performance goal.

This table captures not only first cycle approvals but also multiple cycle approvals. For applications that were approved after multiple cycles, the performance metric is based on the last cycle during which the application was approved.

Table B-1. Aggregate Filings and Approvals for FY 2025 of Original Biosimilar Applications and Category A-F Supplements.

Application Type	Performance Goal: Act on 90 Percent Within	Filed in FY 2025*	Approved in FY 2025†	On Time‡	Overdue‡	Percent on Time
Original Biosimilar Applications	10 Months of the 60-Day Filing Date	17	12	11	1	92%
Resubmitted Original Biosimilar Applications	6 Months of the Receipt Date	25	12	11	1	92%
Original Category A Supplements	3 Months of the Receipt Date	11	10	10	0	100%
Original Category B Supplements	4 Months of the Receipt Date	8	3	3	0	100%
Original Category C Supplements	4 Months of the Receipt Date	0	0	0	0	--
Original Category D Supplements	6 Months of the Receipt Date	6	7	6	1	86%
Original Category E Supplements	10 Months of the Receipt Date	0	0	0	0	--
Original Category F Supplements	10 Months of the Receipt Date	2	1	1	0	100%
Resubmitted Category A Supplements	3 Months of the Receipt Date	0	0	0	0	--
Resubmitted Category B Supplements	4 Months of the Receipt Date	0	0	0	0	--
Resubmitted Category C Supplements	4 Months of the Receipt Date	0	0	0	0	--

Application Type	Performance Goal: Act on 90 Percent Within	Filed in FY 2025*	Approved in FY 2025†	On Time‡	Overdue‡	Percent on Time
Resubmitted Category D Supplements	6 Months of the Receipt Date	0	0	0	0	--
Resubmitted Category E Supplements	6 Months of the Receipt Date	0	0	0	0	--
Resubmitted Category F Supplements	6 Months of the Receipt Date	6	6	6	0	100%
Total	--	75	51	48	3	--§

* For this reporting table, "Filed" counts include applications and supplements that have been filed, are in pending filing status, or have been accepted as a resubmission. Data do not reflect applications and supplements that are unacceptable for filing because of nonpayment of user fees, have been withdrawn within 60 days of receipt, or have been refused to file.

† This column represents applications and supplements approved in FY 2025, regardless of when the application or supplement was received.

‡ The on time and overdue metrics are based on the cycle that received the approval action.

§ Performance is not calculated on combined goals.

B. Performance Enhancement Goals

Tables B-2 and B-3 address section 744I(a)(5)(B) of the FD&C Act, which requires FDA to include an analysis of relevant data to determine whether CDER and CBER have met performance enhancement goals identified in the letters described in section 4001(b) of the Biosimilar User Fee Amendments of 2022 for the applicable fiscal year. This table represents FDA's FY 2025 performance. A link to each performance enhancement goal completed under BsUFA III can be found on FDA's website at https://www.fda.gov/industry/biosimilar-user-fee-amendments/completed-bsufa-iii-deliverables.

In this report, *performance enhancement goals* are defined as any non-review performance goal described in the BsUFA III Commitment Letter with a specified goal date that falls within the applicable fiscal year.

Table B-2. FY 2024 Performance Enhancement Goals (Updated).

Performance Enhancement Goal.	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
Hiring BsUFA Drug Review Staff FY24	9/30/2024	N	-	

Table B-3. FY 2025 Performance Enhancement Goals.

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
ESG Website Update FY24	10/21/2024	Y	10/8/2024	https://www.fda.gov/industry/about-esg/submission-statistics
Quarterly Hiring Reporting Q4 FY24	10/21/2024	Y	10/8/2024	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates FDA sets the target goal date for these postings because the Commitment Letter does not specify a date. FDA achieved timely postings, so no corrective actions are needed.
Quarterly Hiring Reporting Q1 FY25	1/21/2025	Y	1/14/2025	
Quarterly Hiring Reporting Q2 FY25	4/21/2025	N	6/26/2025	
Quarterly Hiring Reporting Q3 FY25	7/21/2025	Y	7/15/2025	
Provide Information on CPA Fee Revenues to BsUFA Annual Financial Report FY24	3/31/2025	Y	10/31/2024	
Publish Financial Plan Updates FY25	3/31/2025	N	7/30/2025	https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans
Publish Implementation Plan Updates FY25	3/31/2025	Y	3/31/2025	https://www.fda.gov/industry/fda-user-fee-programs/resource-capacity-planning-and-modernized-time-reporting
Publish Type 2A Metrics on Public Webpage	3/31/2025	Y	3/31/2025	https://www.fda.gov/media/186037/download?attachment
Publish Revised/Final Supplements Guidance	4/10/2025	N	9/8/2025	https://www.fda.gov/regulatory-information/search-fda-guidance-

				documents/classification-categories-certain-supplements-under-bsufa-iii No corrective action needed because deliverable was completed.
Publish Final Guidance on Labeling for Interchangeable Biosimilars	5/17/2025	N	-	No corrective action needed because deliverable is still underway.
Publish Final Guidance on Alternative Tools to Assess Manufacturing Facilities	5/21/2025	N	9/12/2025	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-tools-assessing-drug-manufacturing-facilities-identified-pending-applications No corrective action needed because deliverable was completed.
Conduct Public Meeting Financial Plan FY25	6/30/2025	N	9/30/2025	https://www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and
Conduct Independent Assessment of Hiring	6/30/2025	Y	3/28/2025	
Publish Independent Assessment of Hiring Report	6/30/2025	N	8/25/2025	https://www.fda.gov/media/188083/download?attachment
Complete ESG Transition to Cloud	9/30/2025	Y	4/14/2025	
Develop and Update Data and Tech Modernization Strategy FY25	9/30/2025	N	-	See corrective actions for additional information.
Hold Public Meeting for Independent Assessment of Hiring	9/30/2025	Y	9/24/2025	https://www.fda.gov/drugs/news-events-human-drugs/prescription-drug-user-fee-act-and-biosimilar-user-fee-amendments-hiring-and-retention-assessment

Publish Draft Guidance on Container Closure	9/30/2025	N	-	See corrective actions for additional information.
Publish Interim Report on Progress of Demonstration Projects	9/30/2025	Y	7/18/2025	https://www.fda.gov/media/187445/download?attachment
Publish Resource Capacity Planning Assessment Report	9/30/2025	Y	9/26/2025	https://www.fda.gov/media/188791/download?attachment
Share ESG Implementation Project Plan (BsUFA Continuous Engagement Meeting) FY25	9/30/2025	Y	9/23/2025	

C. Common Causes and Trends Impacting FDA's Ability to Meet Goals

Table B-4 and B-5 address section 744I(a)(5)(C) of the FD&C Act, which requires FDA to identify the most common causes and trends of external or other circumstances affecting the ability of FDA to meet the review time and performance enhancement goals identified in the letters described in section 4001(b) of the Biosimilar User Fee Amendments of 2022. In addition to presenting the causes and trends initially identified in the last fiscal year's report, this table represents FDA's FY 2024 updated performance results.

Table B-4. FY 2024 Updated Performance Results.

Cause or Trend	Impact on FDA's Commitments
• Small performance cohorts for BPD Type 1 meetings scheduled, BPD Type 2b written response and special protocol assessments • Increasing resource-intensive workload across user fee programs repeatedly strained the same set of staff within relevant offices/divisions	• Because the cohorts of BPD Type 1 meetings scheduled, BPD Type 2b written response and special protocol assessments are small, a single missed goal had a large impact on goal performance. • For the missed goals of BPD Type 4 meetings (respond within 21 days), BPD Type 4 meetings scheduled, and meeting minutes for all meeting types, the increasing workload across user fee programs impacting the same set of key staff contributed to the overall challenge of meeting this goal.

Table B-5 represents FDA's FY 2025 preliminary performance results.

Table B-5. FY 2025 Preliminary Performance Results.

Cause or Trend	Impact on FDA's Commitments
• Small performance cohort for Original Category D supplements and BPD Type 1 Meetings Scheduled • Increasing resource-intensive workload across user fee programs repeatedly strained the same set of staff within relevant offices/divisions	• Because the cohort of Original Category D supplements and BPD Type 1 Meetings Scheduled is small, a single missed goal had a large impact on goal performance. • For the missed goals of BIA meetings scheduled (schedule within 75 days) and BPD Type 2b written response, the increasing workload across user fee programs impacting the same set of key staff contributed to the overall challenge of meeting these goals.

Appendix C: FY 2025 Corrective Action Report

Section 744I(c) of the FD&C Act requires FDA to publicly issue a corrective action report that details its progress in meeting the review and performance enhancement goals identified in the BsUFA III Commitment Letter for the applicable fiscal year.

If each of the review and performance enhancement goals for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary of Health and Human Services can improve and streamline the biosimilar biological product application review process.

For any of the review and performance enhancement goals during the applicable fiscal year that FDA determines were not met, the corrective action report shall include a justification for such determination and a description of the types of circumstances and trends that contributed to missed review goal times; and with respect to performance enhancement goals that were not met, a description of the efforts FDA has put in place to improve the ability of the Agency to meet each goal in the coming fiscal year.

This report satisfies this reporting requirement.

A. Executive Summary

Table C-1 represents FDA's FY 2024 updated performance results for goal types that the Agency was not able to fully report in last year's report. If a goal type is not listed in this table for FY 2024, then the Agency fully reported on it in the last fiscal year's report.[5]

Table C-1. FY 2024 Updated Performance Results.

Goal Type	Circumstances and Trends Impacting the Ability to Meet the Goal Date	Corrective Action Plan
Procedural and Processing	• The BsUFA cohort is small relative to other programs for many performance categories, meaning a single missed goal could have a large impact on performance. • An increasing resource-intensive workload, combined with staffing challenges, across user fee programs repeatedly strained the same set of key staff within relevant offices/divisions.	• FDA continues to assess ways to handle the procedural goals and meeting requests, as well as the increasing review workload, more effectively.

Table C-2 relates to FDA's FY 2025 preliminary performance results missed goals type(s), circumstances and trends impacting FDA's ability to meet the goal date, and the corrective action plan.

[5] https://www.fda.gov/about-fda/user-fee-performance-reports/bsufa-performance-reports.

Table C-2. FY 2025 Preliminary Performance Results.

Goal Type	Circumstances and Trends Impacting the Ability to Meet Goal Date	Corrective Action Plan
Review Performance	• The cohort of Original Category D Supplements is small, meaning that a single missed goal could have a large impact on performance.	• FDA continues to strive to meet all BsUFA review performance goals.
Procedural and Processing	• For the missed goals of BIA meetings scheduled (schedule within 75 days), BPD Type 1 meetings scheduled (schedule within 30 days), and Type 2b Written Response (send within 90 days), the increasing workload across user fee programs impacting the same set of key staff contributed to the overall challenge of meeting these goals.	• FDA continues to assess ways to handle the procedural goals and meeting requests more effectively.

Table C-3 relates to FDA's FY 2025 performance enhancement goal results missed goal types, circumstances and trends impacting FDA's ability to meet the goal date and the corrective action plan.

Table C-3. FY 2025 Performance Enhancement Goal Performance Results.

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Financial Transparency	• The delay in publishing the Five-Year Financial Plans reflects the Agency's commitment to providing accurate and meaningful financial projections.	• FDA plans on meeting these commitments in FY 2026.
Hiring Assessment	• FDA experienced above average staff attrition which resulted in delays in the report publication.	• No corrective action is needed. This represents a one-time occurrence.
Advancing Development of Interchangeable Biosimilar Biological Products	• The guidance is delayed because FDA is working through complex policy issues that arose during review of the guidance.	• FDA will continue to press for expedited review for the next steps in the clearance process.

B. BsUFA Review Goals

The following section addresses section 744I(c)(2)(A) of the FD&C Act, which requires FDA to provide a justification for the determination of review goals missed during FY 2025 and a description of the circumstances and any trends related to missed review goals.

This section presents BsUFA performance and workload information for two different types of goals: (1) FDA's review of applications and supplements pertaining to biosimilar biological products and (2) FDA's meeting management and other procedural goals related to responses and notifications in the biosimilar review process.

This section includes all such BsUFA III goals that were not met with required completion dates in FY 2025. This section also includes FDA's FY 2024 updated performance results for goal types that the Agency was not able to fully report in last year's report. If a goal type is not listed below for FY 2024, then the Agency fully reported on it in the last fiscal year's report.

1. FY 2025 Review Goal Performance Results

Summary of Performance

FDA is currently meeting or exceeding the performance goal for 6 of the 7 applicable goals. There are 16 review goals, but only 7 had applicable submissions. If all non-overdue pending submissions are reviewed on time, FDA has the potential to meet or exceed the performance goal for 8 of the 9 applicable review goals.

Justification

For the missed goal of Original Category D Supplements acted on within 6 months, the cohort of supplements is small, meaning that a single missed goal could have a large impact on performance.

Corrective Actions

FDA continues to strive to meet all BsUFA review performance goals.

2. FY 2025 Procedural and Processing Performance Results

Summary of Performance

FDA missed the following procedural notification and meeting management goals: Biosimilar Initial Advisory Meetings Scheduled (within 75 days), BPD Type 1 Meetings Scheduled (within 30 days), and BPD Type 2b Written Response (within 90 days).

There are 27 procedural and processing performance goals, but only 24 had applicable submissions. FDA is currently meeting or exceeding the performance goal for 21 of the 24 procedural and processing goals.

Justification

For the missed goals of Biosimilar Initial Advisory Meetings Scheduled (within 75 days), BPD Type 1 Meetings Scheduled (within 30 days), and BPD Type 2b Written Response (within 90 days), the increasing workload across user fee programs impacting the same set of key staff contributed to the overall challenge of meeting these goals.

Corrective Actions

FDA continues to assess ways to handle the procedural goals and meeting requests more effectively.

C. BsUFA Performance Enhancement Goals

The following section addresses section 744I(c)(2)(B) of the FD&C Act, which requires FDA to provide, with respect to performance enhancement goals that were not achieved, a description of the efforts FDA has put in place to improve its ability to meet each goal.

This section presents non-review performance goals cited in the BsUFA III Commitment Letter with required completion dates in FY 2025. In this report, *performance enhancement goals* are defined as any non-review performance goal described in the BsUFA III Commitment Letter with a specified goal date that falls within the applicable fiscal year.

1. Financial Transparency

Summary of Performance

FDA missed the goal to publish a BsUFA 5-year financial plan and the subsequent goal to hold a public meeting to present the financial plan. The financial plan, due by March 31, 2025, was published July 30, 2025. The public meeting, due by June 30, 2025, was held September 30, 2025.

Justification

The delay in publishing the Five-Year Financial Plans reflects the Agency's commitment to providing accurate and meaningful financial projections.

Corrective Actions

FDA plans on meeting these commitments in FY 2026.

2. Hiring Assessment

Summary of Performance

FDA missed the BsUFA goal to publish a third-party assessment report on the hiring and retention of program staff. The commitment letter states the report should be published by June 30, 2025. FDA published the report on August 25, 2025.

Justification

FDA experienced above average staff attrition which resulted in delays in the report publication.

Corrective Actions

FDA does not anticipate the replication of these unforeseen circumstances.

3. Advancing Development of Interchangeable Biosimilar Biological Products

Summary of Performance

FDA missed the BsUFA goal to publish a draft guidance on container closure. The guidance, due September 30, 2025, was not published.

Justification

The guidance is delayed because FDA is working through complex policy issues that arose during review of the guidance.

Corrective Actions

FDA will continue to press for expedited review for the next steps in the clearance process.

4. Develop Data and Technology Modernization Strategy

Summary of Performance

FDA missed the BsUFA goal to develop and update FDA's data and technology modernization strategy for fiscal year 2025.

Justification

Driven by the Commissioner's mandate to eliminate siloes and implement enterprise approaches to technology solutions and AI, FDA is currently consolidating agency systems across centers and bringing each center to a shared, modernized platform which supersedes previous data and technology strategy. Given the magnitude of the change and the pace of the consolidations, CDER and CBER are focused on achieving the results. Updates were provided quarterly to industry partners for the last two quarters.

Corrective Actions

FDA will investigate how to continue meeting the spirit of these commitments through regular stakeholder meetings and other approaches.

This report was prepared by FDA's Performance Management Staff in collaboration with FDA's Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research. For information on obtaining additional copies, please contact:

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