Performance Report to Congress

Biosimilar User Fee Act

FY 2023

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 11th year of the BsUFA program and the first year of BsUFA III. The report presents FDA's final performance results in meeting BsUFA goals and commitments for FY 2022 and FDA's preliminary performance results for FY 2023.

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 D of the report. Key highlights for the BsUFA program include the following:

- For the FY 2022 cohort, FDA met or exceeded 16 of the 25 goals. (There were 28 goals, but only 25 had applicable submissions.)

- FDA has the potential to meet or exceed 27 of the 32 goals that apply to the FY 2023 cohort once these actions are completed. (There are 42 goals, but only 32 had 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
ORA	Office of Regulatory Affairs
PDUFA	Prescription Drug User Fee Act
PHS Act	Public Health Service Act
REMS	Risk Evaluation and Mitigation Strategy
WCF	Working Capital Fund

I. 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 2022 and FDA's preliminary performance results for FY 2023. These data represent FDA's performance on submissions received and actions taken as of September 30, 2023. Final FDA performance results for FY 2023 submissions will be presented in the FY 2024 BsUFA performance report and will include final actions for submissions still pending within the BsUFA goal date as of September 30, 2023. 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.

- Unless otherwise noted, all performance data are as of September 30, 2023.

- 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.
- **Resubmitted Supplement with Clinical Data** – A complete response to an action letter for an original supplement with clinical data addressing all identified deficiencies.
- **Manufacturing Supplement** – A request for FDA to approve a change in the manufacturing of an approved biosimilar.
- **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.
- **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 functions essays, 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).
- **Category C Supplement** – A request for FDA to approve a change seeking to remove an approved indication for a licensed biosimilar or interchangeable product.
- **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 B of this report.

II. 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 B.

Table 1. FDA's Performance Review Goals from FY 2023 to FY 2027

BsUFA Submission Type	Goal: Act on Within	FY 23	FY 24	FY 25	FY 26	FY 27
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. FDA's Procedural and Meeting Goals from FY 2023 to FY 2027

BsUFA Submission Type	Goal	FY 23	FY 24	FY 25	FY 26	FY 27
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 Review Issues Identified During the Filing Review for Original Category E and F Supplements	Notify within 74 days	90%	90%	90%	90%	90%
Proprietary Name Submitted During BPD Phase	Review and respond within 180 days	90%	90%	90%	90%	90%
Proprietary Name Submitted During Application Review	Review and respond within 90 days	90%	90%	90%	90%	90%
Procedural Responses						
Major Dispute Resolution	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	Respond within 45 days	90%	90%	90%	90%	90%
Use-Related Risk Analysis Submissions	Respond within 60 days	--	50%	70%	90%	90%
Human Factors Validation Protocol Submissions to Investigational New Drug Applications (INDs)	Respond within 60 days	90%	90%	90%	90%	90%
Meeting Management						
Meeting Requests: Biosimilar Initial Advisory (BIA)	Respond within 21 days	90%	90%	90%	90%	90%
Meeting Requests: BPD Type 1	Respond within 14 days	90%	90%	90%	90%	90%
Meeting Requests: BPD Type 2a	Respond within 21	90%	90%	90%	90%	90%

BsUFA Submission Type	Goal	FY 23	FY 24	FY 25	FY 26	FY 27
	days					
Meeting Requests: BPD Type 2b	Respond within 21 days	90%	90%	90%	90%	90%
Meeting Requests: BPD Type 3	Respond within 21 days	90%	90%	90%	90%	90%
Meeting Requests: BPD Type 4	Respond within 21 days	90%	90%	90%	90%	90%
Scheduling Meetings: BIA	Schedule within 75 days	90%	90%	90%	90%	90%
Scheduling Meetings: BPD Type 1	Schedule within 30 days	90%	90%	90%	90%	90%
Scheduling Meetings: BPD Type 2a	Schedule within 60 days	50%	60%	70%	80%	90%
Scheduling Meetings: BPD Type 2b	Schedule within 90 days	90%	90%	90%	90%	90%
Scheduling Meetings: BPD Type 3	Schedule within 120 days	90%	90%	90%	90%	90%
Scheduling Meetings: BPD Type 4	Schedule within 60 days	90%	90%	90%	90%	90%
Written Response: BIA	Respond within 75 days	90%	90%	90%	90%	90%
Written Response: BPD Type 2a	Respond within 60 days	50%	60%	70%	80%	90%
Written Response: BPD Type 2b	Respond within 90 days	90%	90%	90%	90%	90%
Preliminary Responses: BPD Type 2b	Issue no later than 5 days prior to meeting date	90%	90%	90%	90%	90%
Preliminary Responses: BPD Type 3	Issue no later than 5 days prior to	90%	90%	90%	90%	90%

BsUFA Submission Type	Goal	FY 23	FY 24	FY 25	FY 26	FY 27
	meeting date					
Meeting Minutes: All Meeting Types	Issue within 30 days after meeting date	90%	90%	90%	90%	90%

III. FY 2022 Final BsUFA Performance Summary

The FY 2022 final BsUFA review goal performance results are presented in the tables below. The details of the percentages can be found in Appendix A.

- The *Percent on Time* column presents the percentage of actions completed that were reviewed within the specified goal. Submission types that met or exceeded the performance goal are shown as having met the goal.

Of the 28 BsUFA goal categories, 25 applied to FY 2022 biosimilar biological product submissions. FDA met or exceeded 16 of these 25 goals. No submissions were received for three of the 28 BsUFA goal categories, indicated with an "NA" in Tables 3 and 4 below.

Table 3. FY 2022 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	10 of 11	90%	91%	Yes
Resubmitted Original Biosimilar Applications	6 months	7 of 7	90%	100%	Yes
Original Supplements with Clinical Data	10 months	12 of 16	90%	75%	No
Resubmitted Supplements with Clinical Data	6 months	0 of 0	90%	NA*	NA*
Manufacturing Supplements Requiring Prior Approval	4 months	37 of 40	90%	93%	Yes
Manufacturing Supplements Not Requiring Prior Approval	6 months	31 of 32	90%	97%	Yes

Table 4. FY 2022 Final Procedural and Meeting Goal Performance Results

BsUFA Submission Type	Goal	On Time	Performance Goal	Percent on Time	Goal Met
Procedural Notifications					
Notification of Issues Identified During the Filing Review for Supplements with Clinical Data	Notify within 74 days	8 of 8	90%	100%	Yes
Notification of Planned Review Timeline for Supplements with Clinical Data	Notify within 74 days	8 of 8	90%	100%	Yes
Proprietary Name Submitted During BPD Phase	Review and respond within 180	2 of 12	90%	17%	No
Proprietary Name Submitted During Application Review	Review and respond within 90 days	23 of 24	90%	96%	Yes
Procedural Responses					
Major Dispute Resolution	Respond within 30 days	0 of 0	90%	NA*	NA*
Responses to Clinical Holds	Respond within 30 days	0 of 0	90%	NA*	NA*
Special Protocol Assessments	Respond within 45 days	3 of 3	90%	100%	Yes
Meeting Management					
Meeting Requests: BIA	Respond within 21 days	9 of 9	90%	100%	Yes
Meeting Requests: BPD Type 1	Respond within 14 days	12 of 14	90%	86%	No
Meeting Requests: BPD Type 2	Respond within 21 days	86 of 97	90%	89%	No
Meeting Requests: BPD Type 3	Respond within 21 days	2 of 2	90%	100%	Yes
Meeting Requests: BPD Type 4	Respond within 21 days	11 of 13	90%	85%	No

BsUFA Submission Type	Goal	On Time	Performance Goal	Percent on Time	Goal Met
Scheduling Meetings: BIA	Schedule within 75 days	3 of 4	90%	75%	No
Scheduling Meetings: BPD Type 1	Schedule within 30 days	10 of 14	90%	71%	No
Scheduling Meetings: BPD Type 2	Schedule within 90 days	69 of 77	90%	90%	Yes
Scheduling Meetings: BPD Type 3	Schedule within 120 days	2 of 2	90%	100%	Yes
Scheduling Meetings: BPD Type 4	Schedule within 60 days	10 of 13	90%	77%	No
Written Response: BIA	Respond within 75 days	3 of 3	90%	100%	Yes
Written Response: BPD Type 2	Respond within 90 days	13 of 14	90%	93%	Yes
Preliminary Responses: BPD Type 2	Issue no later than 5 days prior to meeting date	67 of 76	90%	88%	No
Preliminary Responses: BPD Type 3	Issue no later than 5 days prior to meeting date	2 of 2	90%	100%	Yes
Meeting Minutes: All Meeting Types	Issue within 30 days after meeting date	71 of 76	90%	93%	Yes

* In all submission types marked “NA,” performance goals do not apply because no submissions were received.

IV. FY 2023 Preliminary BsUFA Performance Summary

FY 2023 BsUFA performance results are presented in Tables 5 and 6.

- The *Progress* column shows how much of the cohort has been acted on by presenting the number of submissions that had actions taken in FY 2023 or were overdue as of September 30, 2023, 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 *Percent on Time* column presents the percentage of actions completed that were within the goal as of September 30, 2023. Actions that were pending and not yet past the goal date as of September 30, 2023, are excluded from this calculation. Please see Appendix A for the details of these percentages.

- 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 27 of the 32 applicable goals that apply to the FY 2023 cohort once these actions are completed. There are 42 goals, but no submissions were received for 10 BsUFA goal categories that are indicated with an "NA" in Tables 5 and 6.

Table 5. FY 2023 Preliminary Review Goal Performance Results

BsUFA Submission Type	Progress	Goal: Act on Within	Performance Goal	Percent on Time	Highest Possible Performan
Biosimilar Applications and Supplements					
Original Biosimilar Product Applications	0 of 19 complete	10 months from 60-day filing date	90%	--	100%
Resubmitted Original Biosimilar Applications	4 of 12 complete	6 months	90%	75%	92%
Original Category A Supplements	5 of 5 complete	3 months	70%	80%	80%
Original Category B Supplements	1 of 1 complete	4 months	70%	100%	100%
Original Category C Supplements	0 of 0 complete	4 months	70%	NA*	NA*
Original Category D Supplements	8 of 11 complete	6 months	70%	100%	100%
Original Category E Supplements	0 of 0 complete	10 months	90%	NA*	NA*
Original Category F Supplements	0 of 2 complete	10 months	90%	--	100%
Resubmitted Category A Supplements	0 of 0 complete	3 months	70%	NA*	NA*
Resubmitted Category B Supplements	0 of 0 complete	4 months	70%	NA*	NA*
Resubmitted Category C Supplements	0 of 0 complete	4 months	70%	NA*	NA*
Resubmitted Category D Supplements	0 of 0 complete	6 months	70%	NA*	NA*
Resubmitted Category E Supplements	0 of 0 complete	6 months	90%	NA*	NA*
Resubmitted Category F Supplements	0 of 0 complete	6 months	90%	NA*	NA*
Manufacturing Supplements Requiring Prior Approval	26 of 47 complete	4 months	90%	100%	100%
Manufacturing Supplements Not Requiring Prior Approval	20 of 41 complete	6 months	90%	100%	100%

* In all submission types marked “NA,” performance goals do not apply because no submissions were received.

Table 6. FY 2023 Preliminary Procedural and Processing Goal Performance Results

BsUFA Submission Type	Progress	Goal	Performance Goal	Percent on Time	Highest Possible Performan
Procedural Notifications					
Notification of Receipt and Planned Review Timeline for Original Category A through D Supplements	19 of 19 complete	Review and respond within 60 days	90%	100%	100%
Notification of Issues Identified During the Filing Review for Original Category E and F Supplements	1 of 2 complete	Review and respond within 74 days	90%	100%	100%
Proprietary Name Submitted During BPD Phase	9 of 18 complete	Review and respond within 180 days	90%	89%	94%
Proprietary Name Submitted During Application Review	31 of 40 complete	Review and respond within 90 days	90%	100%	100%
Procedural Responses					
Major Dispute Resolution	0 of 0 complete	Respond within 30 days	90%	NA*	NA*
Responses to Clinical Holds	0 of 0 complete	Respond within 30 days	90%	NA*	NA*
Special Protocol Assessments	3 of 4 complete	Respond within 45 days	90%	67%	75%
Human Factors Protocol Submissions to INDs	5 of 6 complete	Respond within 60 days	90%	0%	17%
Meeting Management					
Meeting Requests: BIA	13 of 13 complete	Respond within 21 days	90%	92%	92%

BsUFA Submission Type	Progress	Goal	Performance Goal	Percent on Time	Highest Possible Performan
Meeting Requests: BPD Type 1**	7 of 11 complete	Respond within 14 days	90%	100%	100%
Meeting Requests: BPD Type 2a	35 of 36 complete	Respond within 21 days	90%	86%	86%
Meeting Requests: BPD Type 2b	50 of 51 complete	Respond within 21 days	90%	90%	90%
Meeting Requests: BPD Type 3	1 of 1 complete	Respond within 21 days	90%	100%	100%
Meeting Requests: BPD Type 4	23 of 23 complete	Respond within 21 days	90%	91%	91%
Scheduling Meetings: BIA	10 of 10 complete	Schedule within 75 days	90%	90%	90%
Scheduling Meetings: BPD Type 1**	4 of 8 complete	Schedule within 30 days	90%	100%	100%
Scheduling Meetings: BPD Type 2a	19 of 19 complete	Schedule within 60 days	50%	74%	74%
Scheduling Meetings: BPD Type 2b	41 of 42 complete	Schedule within 90 days	90%	90%	90%
Scheduling Meetings: BPD Type 3	1 of 1 complete	Schedule within 120 days	90%	100%	100%
Scheduling Meetings: BPD Type 4	23 of 23 complete	Schedule within 60 days	90%	70%	70%
Written Response: BIA	2 of 2 complete	Respond within 75 days	90%	100%	100%
Written Response: BPD Type 2a	12 of 16 complete	Respond within 60 days	50%	100%	100%
Written Response: BPD Type 2b	6 of 8 complete	Respond within 90 days	90%	83%	88%

BsUFA Submission Type	Progress	Goal	Performance Goal	Percent on Time	Highest Possible Performan
Preliminary Responses: BPD Type 2b	31 of 39 complete	Issue no later than 5 days prior to meeting date	90%	87%	90%
Preliminary Responses: BPD Type 3	0 of 1 complete	Issue no later than 5 days prior to meeting date	90%	--	100%
Meeting Minutes: All Meeting Types	53 of 70 complete	Issue within 30 days after meeting date	90%	89%	91%

* In all submission types marked "NA," performance goals do not apply because no submissions were received.

** 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 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 2024 BsUFA performance report.

V. BsUFA Workload

A. Workload: FY 2019 to FY 2023

Tables 7 and 8 present the workload numbers from FY 2019 to FY 2023.

Table 7. Review Workload from FY 2019 to FY 2023

BsUFA Workload	FY 2019	FY 2020	FY 2021	FY 2022*	FY 2023
Biosimilar Applications and Supplements					
Original Biosimilar Product Applications	7	8	10	11	19
Resubmitted Original Biosimilar Applications	4	1	5	7	12
Original Supplements with Clinical Data	12	2	10	16	--
Resubmitted Supplements with Clinical Data	0	1	1	0	--
Original Category A Supplements	--	--	--	--	5
Original Category B Supplements	--	--	--	--	1
Original Category C Supplements	--	--	--	--	0
Original Category D Supplements	--	--	--	--	11
Original Category E Supplements	--	--	--	--	0
Original Category F Supplements	--	--	--	--	2
Resubmitted Category A Supplements	--	--	--	--	0
Resubmitted Category B Supplements	--	--	--	--	0
Resubmitted Category C Supplements	--	--	--	--	0
Resubmitted Category D Supplements	--	--	--	--	0
Resubmitted Category E Supplements	--	--	--	--	0
Resubmitted Category F Supplements	--	--	--	--	0
Manufacturing Supplements Requiring Prior Approval	22	43	50	40	47
Manufacturing Supplements Not Requiring Prior Approval	28	31	40	32	41

* FY 2022 numbers were changed to reflect updates to the data presented in the FY 2022 BsUFA performance report.

Table 8. Procedural and Meeting Workload from FY 2019 to FY 2023

BsUFA Workload	FY 2019	FY 2020	FY 2021	FY 2022*	FY 2023
Procedural Notifications					
Notification of Issues Identified During the Filing Review for Supplements with Clinical Data	7	1	7	8	--
Notification of Planned Review Timeline for Supplements with Clinical Data	6	1	7	8	--
Notification of Receipt and Planned Review Timeline for Original Category A through D Supplements	--	--	--	--	19
Notification of Issues Identified During the Filing Review for Original Category E and F Supplements	--	--	--	--	2
Review of Proprietary Names Submitted During BPD Phase	3	6	8	12	18
Review of Proprietary Names Submitted During Application Review	15	10	15	24	40
Procedural Responses					
Major Dispute Resolution	0	0	0	0	0
Responses to Clinical Holds	1	0	2	0	0
Special Protocol Assessments	2	2	1	3	4
Human Factors Protocol Submissions to INDs	--	--	--	--	6
Meeting Management					
Meeting Requests: BIA ^	11	8	6	9	13
Meeting Requests: BPD Type 1 ^	9	6	4	14	11**
Meeting Requests: BPD Type 2 ^***	77	67	90	97	--
Meeting Requests: BPD Type 2a ^	--	--	--	--	36
Meeting Requests: BPD Type 2b ^	--	--	--	--	51
Meeting Requests: BPD Type 3 ^	9	4	7	2	1
Meeting Requests: BPD Type 4 ^	8	8	10	13	23
Scheduling Meetings: BIA	7	4	3	4	10
Scheduling Meetings: BPD Type 1	8	6	4	14	8**
Scheduling Meetings: BPD Type 2***	55	44	64	77	--
Scheduling Meetings: BPD Type 2a	--	--	--	--	19

BsUFA Workload	FY 2019	FY 2020	FY 2021	FY 2022*	FY 2023
Scheduling Meetings: BPD Type 2b	--	--	--	--	42
Scheduling Meetings: BPD Type 3	9	3	6	2	1
Scheduling Meetings: BPD Type 4	7	8	10	13	23
Written Response: BIA	0	2	2	3	2
Written Response: BPD Type 2***	16	21	23	14	--
Written Response: BPD Type 2a	--	--	--	--	16
Written Response: BPD Type 2b	--	--	--	--	8
Preliminary Responses: BPD Type 2	54	44	64	76	--
Preliminary Responses: BPD Type 2b	--	--	--	--	39
Preliminary Responses: BPD Type 3	9	3	6	2	1
Meeting Minutes: All Meeting Types	71	52	68	76	70

* FY 2022 numbers were changed to reflect updates to the data presented in the FY 2022 BsUFA performance report.

** 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 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 2024 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.

^ 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.

VI. Additional Reporting Requirements

Section 408 of the Food and Drug Administration Safety and Innovation Act added section 715(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which requires that, beginning in FY 2014, 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, 2023, 84 351(k) applications were accepted for filing by FDA.

As of September 30, 2023, 52 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;

- 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 two biosimilar product applications that have not received an action from either the FY 2022 or earlier cohorts.

Table 9. Original Biosimilar Product Applications and Resubmitted Original Biosimilar Product Applications Filed* and Approvals to Such Applications

Application Type	FY 2023 (Filed*/Approved as of 9/30/2023)
Original Biosimilar Product Applications	19/0
Resubmitted Original Biosimilar Product Applications	12/1

* 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 a nonpayment of user fees, have been withdrawn within 60 days of receipt, or have been refused to file.

VII. 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 Regulatory Affairs, 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 Regulatory Affairs, 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.

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, ORA, 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 14 individuals in FY 2023 to enhance the biosimilar biological product review program. The data in Table 10 show the changes from FY 2022 to FY 2023 in the number of individuals hired as agreed upon in the BsUFA III Commitment Letter.

Table 10. Change in the Number of Individuals Hired as Agreed Upon in the BsUFA III Commitment Letter and Remaining Vacancies

Center	Number Hired in FY 2022*	Number Hired in FY 2023	Change in Number Hired	Remaining Vacancies in FY 2022*	Remaining Vacancies in FY 2023	Change in Number of Remaining Vacancies
CDER	0	7	7	0	7	7
CBER	0	0	0	0	0	0
ORA	0	0	0	0	0	0
OC	0	0	0	0	0	0
Total	**0**	**7**	**7**	**0**	**7**	**7**

* BsUFA III became effective in FY 2023; therefore, there are no BsUFA III hires or remaining vacancies in FY 2022.

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 11 show the number of FTEs funded by fees collected and the number of FTEs funded by budget authority in FY 2023 by each division within CDER, CBER, ORA 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 be presented “by each division,” the information in this table is broken down to the office level for the Centers, ORA, 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 for FY 2023 are those FTEs as of September 30, 2023.

Table 11. 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 the Number of FTEs Funded by Budget Authority	Number of FTEs Funded by Fees		Change in the Number of FTEs Funded by Fees
	FY 2022	FY 2023		FY 2022	FY 2023	
CDER						
Office of Communications	1.21	1.27	0.06	1.01	1.44	0.43
Office of Compliance	1.54	1.16	-0.38	0.21	0.65	0.44
Office of the Center Director	1.17	1.12	-0.05	0	0.17	0.17
Office of Executive Programs	1.38	1.78	0.4	1.37	1.67	0.3
Office of Generic Drugs	0.0	0.0	-0.04	0	0.00	0
Office of Medical Policy	0.51	1.11	0.6	0	0.00	0
Office of Management	2.4	2.23	-0.17	4.99	6.5	1.51
Office of New Drugs	15.75	9	-6.75	23.79	42.05	18.26
Office of Pharmaceutical Quality	17.79	13.79	-4	34.62	53.96	19.34
Office of Regulatory Policy	0.0	1.26	1.26	2.13	1.15	-0.98
Office of Surveillance and Epidemiology	6.0	4.41	-1.54	1.82	5.06	3.24
Office of Strategic Programs	1.01	1.42	0.41	1.81	1.93	0.12
Office of Translational Sciences	6.4	7.39	0.99	19.50	21.7	2.21
Other Offices	0.0	0.22	0.22	0.00	0.00	0
Working Capital Fund (WCF)	2.5	3.27	0.77	4.73	3.27	-1.46
CBER						

Office of Biostatistics and Epidemiology / Office of Biostatistics and Pharmacovigilance†	0.00	0.02	0.02	0.00	0.00	0.00
Office of Blood Research and Review	0.00	0.01	0.01	0.00	0.00	0.00
Office of Compliance and Biologics Quality	0.32	0.05	-0.27	0.00	0.06	0.06
Office of Tissues and Advanced Therapies / Office of Therapeutic Products‡ §	0.30	-0.03	-0.33	0.00	0.08	0.08
Office of Vaccines Research and Review	0.29	0.06	-0.23	0.00	0.00	0.00
Office of Communication Outreach and Development	0.06	0.01	-0.05	0.00	0.03	0.03
Office of the Center Director	0.18	0.06	-0.13	0.00	0.04	0.04
Office of Regulatory Operations¶	0.09	0.04	-0.05	0.00	0.09	0.09
Office of Management	0.19	0.01	-0.18	0.00	0.04	0.04
Office of Information Management and Technology	0.01	0.00	-0.01	0.00	0.00	0.00
Working Capital Fund	0.06	0.02	-0.03	0.00	0.00	0.00
OC						
Office of the Chief Counsel	1.10	1.60	0.50	1.24	1.05	-0.19
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	0.85	0.85	0.70	0.56	-0.14
Office of Operations	2.60	3.19	0.59	2.18	2.10	-0.08
Office of Policy, Legislation, and International Affairs	0.90	1.69	0.79	1.00	1.11	0.11
WCF	0.50	0.27	-0.23	0.00	0.67	0.67
ORA						
Office of Biological Products Operations	0	0	0	7	6.4	-0.6
WCF	0.40	0.40	0	0.48	0.49	0.01

* This table includes BsUFA program FTEs calculated through WCF assessments for certain centrally administered services provided to CDER, CBER, ORA, and OC. 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.

† The Office of Biostatistics and Epidemiology was reorganized to the Office of Biostatistics and Pharmacovigilance in FY 2023.
‡ In FY 2023, CBER over-projected the user fee spending in the Office of Therapeutic Products that exceeded the process FTE limit. This resulted in a negative budget authority FTE (-0.03).
§ CBER's Office of Tissues and Advanced Therapies was reorganized to the Office of Therapeutic Products in FY 2023.
¶ The FY 2023 reorganization created a new office in CBER—namely, the Office of Regulatory Operations. Prior to this reorganization, this office was under the Office the Center Director.

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 12 provides data for the BsUFA fee revenue amounts and process costs for FY 2022 and FY 2023, as well as data for the changes in these amounts from FY 2022 to FY 2023. 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 2023) and prior fiscal year (FY 2022).

The process for setting the annual target revenue is set forth in the statute. For FY 2023, the base revenue amount is the FY 2022 inflation adjusted fee revenue amount of $43,376,922. The FY 2023 base revenue amount was adjusted for inflation. FDA did not make an adjustment to the fee amount pursuant to the capacity planning adjustment. FDA applied a downward operating reserve adjustment of $7,099,898, an amount equivalent to 10 weeks of FY 2023 operations. This resulted in a target revenue amount of $41,600,000 (rounded to the nearest thousand) for FY 2023. In FY 2023, FDA had net collections of $60 million in BsUFA fees, spent $63 million in user fees for the BsUFA program, and carried forward a cumulative balance of $41 million for future fiscal years. Detailed financial information for the BsUFA user fee program can be found in the FY 2023 BsUFA financial report.

In FY 2023, BsUFA obligations increased approximately $15,902,559 from FY 2022. The increase in BsUFA fee fund obligations was largely attributable to increased payroll expenses.

Table 12. Changes in the Average Total Cost Per FTE in the Biosimilar Biological Product Review Program

Revenue/Cost	FY 2022	FY 2023	Change from FY 2022 to FY 2023
Fee Revenue Amounts (Net Collections)	$43,106,548.00	$59,629,003.00	+38%
Process Cost (Cost of Activities)	$68,521,689.00	$86,101,288.00	+26%
Average Total Cost Per FTE	**$202,994.00**	**$218,542.00**	**+8%**

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, ORA, and OC. Accordingly, Table 13 provides the number of employees within CDER, CBER, ORA, and OC, as of September 30, 2023, 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 13. Time Reporting Requirement for FY 2023

Center	FTEs for Which Time Reporting Is Required	FTEs for Which Time Reporting Is Not Required
CDER	5,739	0
CBER	1,260	8
ORA	4,592	0
OC	61	2,606
Total	**11,652**	**2,614**

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

Table 14 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 14. Average FTE Hours Required to Complete Review of Biosimilar Biological Product Applications

Application Type	Average FTE Hours Required to Complete Application Reviews FY 2022	Average FTE Hours Required to Complete Application Reviews FY 2023	Change from FY 2022 to FY 2023
Original Biosimilar Product Applications	4,302	3,997	-305
Total	**4,302**	**3,997**	**-305**

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 2022 to the 3-year average ending in FY 2023. 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: Performance Calculations

The tables in this appendix detail the final performance data for FY 2022 and the preliminary performance data for the FY 2023 cohort of submissions. These data include the number of submissions reviewed on time (i.e., acted on by the BsUFA goal date) or overdue (i.e., acted on past the goal date or pending past the goal date) and the percent on time (i.e., the final performance with no actions pending within the BsUFA goal date for FY 2022 and current performance for FY 2023). The number of submissions not yet acted on but still pending within the BsUFA goal date (i.e., pending within goal) is also provided, along with the highest possible percent of reviews that may be completed on time. The FY 2022 performance data presented here have been updated from the preliminary performance information reported in the FY 2022 BsUFA performance report.

A. Review Goal Performance

Table A- 1. Original Biosimilar Applications

Original Biosimilar Product Applications	FY 2022	FY 2023
Total Filed Submissions (Workload)	11	19
Pending Within Goal	0	19
On Time	10	0
Overdue	1*	0
Performance: % On Time	91%	--†
Highest Possible Performance	91%	100%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Met**	**Currently Meeting, Pending**

* Includes one overdue pending submission.
† Performance cannot be calculated as all submissions are currently pending within goal.

Table A- 2. Resubmitted Original Biosimilar Applications

Resubmitted Original Biosimilar Applications	FY 2022	FY 2023
Total Submissions (Workload)	7	12
Pending Within Goal	0	8
On Time	7	3
Overdue	0	1*
Performance: % On Time	100%	75%
Highest Possible Performance	100%	92%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Met**	**Currently Not Meeting, Pending**

* Includes one overdue pending submission.

Table A- 3. Original Supplements with Clinical Data

Original Supplements with Clinical Data	FY 2022	FY 2023†
Total Filed Submissions (Workload)	16	--
Pending Within Goal	0	--
On Time	12	--
Overdue	4	--
Performance: % On Time	75%	--
Highest Possible Performance	75%	--
BsUFA Goal: On Time Target %	90%	--
Goal Met Status	**Goal Not Met**	**--**

† Not a performance goal for this fiscal year.

Table A- 4. Resubmitted Supplements with Clinical Data

Resubmitted Supplements with Clinical Data	FY 2022	FY 2023†
Total Submissions (Workload)	0	--
Pending Within Goal	0	--
On Time	0	--
Overdue	0	--
Performance: % On Time	NA	--
Highest Possible Performance	NA	--
BsUFA Goal: On Time Target %	90%	--
Goal Met Status	**NA**	**--**

† Not a performance goal for this fiscal year.

Table A- 5. Original Category A Supplements

Original Category A Supplements	FY 2022†	FY 2023
Total Filed Submissions (Workload)	--	5
Pending Within Goal	--	0
On Time	--	4
Overdue	--	1*
Performance: % On Time	--	80%
Highest Possible Performance	--	80%
BsUFA Goal: On Time Target %	--	70%
Goal Met Status	**--**	**Will Meet Goal**

* Includes one overdue pending submission.
† Not a performance goal for this fiscal year.

Table A- 6. Original Category B Supplements

Original Category B Supplements	FY 2022†	FY 2023
Total Filed Submissions (Workload)	--	1
Pending Within Goal	--	0
On Time	--	1
Overdue	--	0
Performance: % On Time	--	100%
Highest Possible Performance	--	100%
BsUFA Goal: On Time Target %	--	70%
Goal Met Status	**--**	**Will Meet Goal**

† Not a performance goal for this fiscal year.

Table A- 7. Original Category C Supplements

Original Category C Supplements	FY 2022†	FY 2023
Total Filed Submissions (Workload)	--	0
Pending Within Goal	--	0
On Time	--	0
Overdue	--	0
Performance: % On Time	--	NA
Highest Possible Performance	--	NA
BsUFA Goal: On Time Target %	--	70%
Goal Met Status	**--**	**NA**

† Not a performance goal for this fiscal year.

Table A- 8. Original Category D Supplements

Original Category D Supplements	FY 2022†	FY 2023
Total Filed Submissions (Workload)	--	11
Pending Within Goal	--	3
On Time	--	8
Overdue	--	0
Performance: % On Time	--	100%
Highest Possible Performance	--	100%
BsUFA Goal: On Time Target %	--	70%
Goal Met Status	**--**	**Will Meet Goal**

† Not a performance goal for this fiscal year.

Table A- 9. Original Category E Supplements

Original Category E Supplements	FY 2022†	FY 2023
Total Filed Submissions (Workload)	--	0
Pending Within Goal	--	0
On Time	--	0
Overdue	--	0
Performance: % On Time	--	NA
Highest Possible Performance	--	NA
BsUFA Goal: On Time Target %	--	90%
Goal Met Status	**--**	**NA**

† Not a performance goal for this fiscal year.

Table A- 10. Original Category F Supplements

Original Category F Supplements	FY 2022†	FY 2023
Total Filed Submissions (Workload)	--	2
Pending Within Goal	--	2
On Time	--	0
Overdue	--	0
Performance: % On Time	--	--*
Highest Possible Performance	--	100%
BsUFA Goal: On Time Target %	--	90%
Goal Met Status	**--**	**Currently Meeting, Pending**

† Not a performance goal for this fiscal year.
* Performance cannot be calculated as all submissions are currently pending within goal.

Table A- 11. Resubmitted Category A Supplements

Resubmitted Category A Supplements	FY 2022†	FY 2023
Total Filed Submissions (Workload)	--	0
Pending Within Goal	--	0
On Time	--	0
Overdue	--	0
Performance: % On Time	--	NA
Highest Possible Performance	--	NA
BsUFA Goal: On Time Target %	--	70%
Goal Met Status	**--**	**NA**

† Not a performance goal for this fiscal year.

Table A- 12. Resubmitted Category B Supplements

Resubmitted Category B Supplements	FY 2022†	FY 2023
Total Filed Submissions (Workload)	--	0
Pending Within Goal	--	0
On Time	--	0
Overdue	--	0
Performance: % On Time	--	NA
Highest Possible Performance	--	NA
BsUFA Goal: On Time Target %	--	70%
Goal Met Status	**--**	**NA**

† Not a performance goal for this fiscal year.

Table A- 13. Resubmitted Category C Supplements

Resubmitted Category C Supplements	FY 2022†	FY 2023
Total Filed Submissions (Workload)	--	0
Pending Within Goal	--	0
On Time	--	0
Overdue	--	0
Performance: % On Time	--	NA
Highest Possible Performance	--	NA
BsUFA Goal: On Time Target %	--	70%
Goal Met Status	**--**	**NA**

† Not a performance goal for this fiscal year.

Table A- 14. Resubmitted Category D Supplements

Resubmitted Category D Supplements	FY 2022†	FY 2023
Total Filed Submissions (Workload)	--	0
Pending Within Goal	--	0
On Time	--	0
Overdue	--	0
Performance: % On Time	--	NA
Highest Possible Performance	--	NA
BsUFA Goal: On Time Target %	--	70%
Goal Met Status	**--**	**NA**

† Not a performance goal for this fiscal year.

Table A- 15. Resubmitted Category E Supplements

Resubmitted Category E Supplements	FY 2022†	FY 2023
Total Filed Submissions (Workload)	--	0
Pending Within Goal	--	0
On Time	--	0
Overdue	--	0
Performance: % On Time	--	NA
Highest Possible Performance	--	NA
BsUFA Goal: On Time Target %	--	90%
Goal Met Status	**--**	**NA**

† Not a performance goal for this fiscal year.

Table A- 16. Resubmitted Category F Supplements

Resubmitted Category F Supplements	FY 2022†	FY 2023
Total Filed Submissions (Workload)	--	0
Pending Within Goal	--	0
On Time	--	0
Overdue	--	0
Performance: % On Time	--	NA
Highest Possible Performance	--	NA
BsUFA Goal: On Time Target %	--	90%
Goal Met Status	**--**	**NA**

† Not a performance goal for this fiscal year.

Table A- 17. Manufacturing Supplements Requiring Prior Approval

Manufacturing Supplements Requiring Prior Approval	FY 2022	FY 2023
Total Filed Submissions (Workload)	40	47
Pending Within Goal	0	21
On Time	37	26
Overdue	3	0
Performance: % On Time	93%	100%
Highest Possible Performance	93%	100%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Met**	**Currently Meeting, Pending**

Table A- 18. Manufacturing Supplements Not Requiring Prior Approval

Manufacturing Supplements Not Requiring Prior Approval	FY 2022	FY 2023
Total Filed Submissions (Workload)	32	41
Pending Within Goal	0	21
On Time	31	20
Overdue	1	0
Performance: % On Time	97%	100%
Highest Possible Performance	97%	100%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Met**	**Currently Meeting, Pending**

B. Procedural and Processing Goal Performance

1. Procedural Notifications

Table A- 19. Notification of Issues Identified During the Filing Review for Supplements with Clinical Data

Notification of Issues Identified During the Filing Review for Supplements with Clinical Data	FY 2022	FY 2023†
Total Filed Submissions (Workload)	8	--
Pending Within Goal	0	--
On Time	8	--
Overdue	0	--
Performance: % On Time	100%	--
Highest Possible Performance	100%	--
BsUFA Goal: On Time Target %	90%	--
Goal Met Status	**Goal Met**	**--**

† Not a performance goal for this fiscal year.

Table A- 20. Notification of Planned Review Timeline for Supplements with Clinical Data

Notification of Planned Review Timeline for Supplements with Clinical Data	FY 2022	FY 2023†
Total Filed Submissions (Workload)	8	--
Pending*	0	--
In 74-Day Letter	8	--
Not in 74-Day Letter	0	--
Performance: % On Time	100%	--
Highest Possible Performance	100%	--
BsUFA Goal: On Time Target %	90%	--
Goal Met Status	**Goal Met**	**--**

* "Pending" includes only those notification commitments that have not been issued and are within 74 days of FDA's receipt of the original submission.
† Not a performance goal for this fiscal year.

Table A- 21. Notification of Receipt and Planned Review Timeline for Original Category A Through F Supplements

Notification of Receipt and Planned Review Timeline for Original Category A Through F Supplements	FY 2022†	FY 2023
Total Filed Submissions (Workload)	--	19
Pending Within Goal	--	0
On Time	--	19
Overdue	--	0
Performance: % On Time	--	100%
Highest Possible Performance	--	100%
BsUFA Goal: On Time Target %	--	90%
Goal Met Status	**--**	**Will Meet Goal**

† Not a performance goal for this fiscal year.

Table A- 22. Notification of Issues Identified During the Filing Review for Original Category E and F Supplements

Notification of Issues Identified During the Filing Review for Original Category E and F Supplements	FY 2022†	FY 2023
Total Filed Submissions (Workload)	--	2
Pending*	--	1
In 74-Day Letter	--	1
Not in 74-Day Letter	--	0
Performance: % On Time	--	100%
Highest Possible Performance	--	100%
BsUFA Goal: On Time Target %	--	90%
Goal Met Status	**--**	**Currently Meeting, Pending**

* "Pending" includes only those notification commitments that have not been issued and are within 74 days of FDA's receipt of the original submission.
† Not a performance goal for this fiscal year.

Table A- 23. Review of Proprietary Names Submitted During BPD Phase

Table A-23. Review of Proprietary Names	FY 2022	FY 2023
Total Submissions (Workload)	12	18
Pending Within Goal	0	9
On Time	2	8
Overdue	10*	1
Performance: % On Time	17%	89%
Highest Possible Performance	17%	94%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Not Met**	**Currently Not Meeting, Pending**

* Includes three overdue pending submissions.

Table A- 24. Review of Proprietary Names Submitted During Application Review

Review of Proprietary Names Submitted During Application Review	FY 2022	FY 2023
Total Submissions (Workload)	24	40
Pending Within Goal	0	9
On Time	23	31
Overdue	1	0
Performance: % On Time	96%	100%
Highest Possible Performance	96%	100%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Met**	**Currently Meeting, Pending**

2. Procedural Responses

Table A- 25. Major Dispute Resolution

Major Dispute Resolution	FY 2022	FY 2023
Total Submissions (Workload)	0	0
Pending Within Goal	0	0
On Time	0	0
Overdue	0	0
Performance: % On Time	NA	NA
Highest Possible Performance	NA	NA
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**NA**	**NA**

Table A- 26. Responses to Clinical Holds

Responses to Clinical Holds	FY 2022	FY 2023
Total Submissions (Workload)	0	0
Pending Within Goal	0	0
On Time	0	0
Overdue	0	0
Performance: % On Time	NA	NA
Highest Possible Performance	NA	NA
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**NA**	**NA**

Table A- 27. Special Protocol Assessments

Special Protocol Assessments*	FY 2022	FY 2023
Total Submissions (Workload)	3	4
Pending Within Goal	0	1
On Time	3	2
Overdue	0	1
Performance: % On Time	100%	67%
Highest Possible Performance	100%	75%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Met**	**Will Not Meet Goal**

* There were no resubmitted Special Protocol Assessments received in FY 2022.

Table A- 28. Human Factors Protocol Submissions to INDs

Human Factors Protocol Submissions to INDs	FY 2022†	FY 2023
Total Submissions (Workload)	--	6
Pending Within Goal	--	1
On Time	--	0
Overdue	--	5*
Performance: % On Time	--	0%
Highest Possible Performance	--	17%
BsUFA Goal: On Time Target %	--	90%
Goal Met Status	**--**	**Will Not Meet Goal**

* Includes four overdue pending submissions.
† Not a performance goal for this fiscal year.

3. Meeting Management[3]

Table A- 29. Responses to Meeting Requests: Biosimilar Initial Advisory

Responses to Meeting Requests: Biosimilar Initial Advisory	FY 2022	FY 2023
Total Submissions (Workload)	9	13
Pending Within Goal	0	0
On Time	9	12
Overdue	0	1
Performance: % On Time	100%	92%
Highest Possible Performance	100%	92%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Met**	**Will Meet Goal**

[3] Not all meeting requests are granted; therefore, the number of meetings scheduled may differ from the number of meeting requests received. Not all scheduled meetings are held; therefore, the number of meeting minutes may differ from the number of meetings scheduled.

Table A- 30. Responses to Meeting Requests: BPD Type 1

Responses to Meeting Requests: BPD Type 1	FY 2022	FY 2023
Total Submissions (Workload)	14	11
Pending Within Goal	0	4
On Time	12	7
Overdue	2	0
Performance: % On Time	86%	100%
Highest Possible Performance	86%	100%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Not Met**	**Currently Meeting, Pending**

Table A- 31. Responses to Meeting Requests: BPD Type 2a

Responses to Meeting Requests: BPD Type 2a	FY 2022†	FY 2023
Total Submissions (Workload)	--	36
Pending Within Goal	--	1
On Time	--	30
Overdue	--	5
Performance: % On Time	--	86%
Highest Possible Performance	--	86%
BsUFA Goal: On Time Target %	--	90%
Goal Met Status	**--**	**Will Not Meet Goal**

† Not a performance goal for this fiscal year.

Table A- 32. Responses to Meeting Requests: BPD Type 2b

Responses to Meeting Requests: BPD Type 2b	FY 2022†	FY 2023
Total Submissions (Workload)	--	51
Pending Within Goal	--	1
On Time	--	45
Overdue	--	5
Performance: % On Time	--	90%
Highest Possible Performance	--	90%
BsUFA Goal: On Time Target %	--	90%
Goal Met Status	**--**	**Currently Meeting, Pending**

† Not a performance goal for this fiscal year.

Table A- 33. Responses to Meeting Requests: BPD Type 3

Responses to Meeting Requests: BPD Type 3	FY 2022	FY 2023
Total Submissions (Workload)	2	1
Pending Within Goal	0	0
On Time	2	1
Overdue	0	0
Performance: % On Time	100%	100%
Highest Possible Performance	100%	100%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Met**	**Will Meet Goal**

Table A- 34. Responses to Meeting Requests: BPD Type 4

Responses to Meeting Requests: BPD Type 4	FY 2022	FY 2023
Total Submissions (Workload)	13	23
Pending Within Goal	0	0
On Time	11	21
Overdue	2	2
Performance: % On Time	85%	91%
Highest Possible Performance	85%	91%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Not Met**	**Will Meet Goal**

Table A- 35. Scheduling Meetings: Biosimilar Initial Advisory

Scheduling Meetings: Biosimilar Initial Advisory	FY 2022	FY 2023
Total Submissions (Workload)	4	10
Pending Within Goal	0	0
On Time	3	9
Overdue	1	1
Performance: % On Time	75%	90%
Highest Possible Performance	75%	90%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Not Met**	**Will Meet Goal**

Table A- 36. Scheduling Meetings: BPD Type 1

Scheduling Meetings: BPD Type 1	FY 2022	FY 2023
Total Submissions (Workload)	14	8
Pending Within Goal	0	4
On Time	10	4
Overdue	4	0
Performance: % On Time	71%	100%
Highest Possible Performance	71%	100%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Not Met**	**Currently Meeting, Pending**

Table A- 37. Scheduling Meetings: BPD Type 2

Scheduling Meetings: BPD Type 2	FY 2022	FY 2023†
Total Submissions (Workload)	77	--
Pending Within Goal	0	--
On Time	69	--
Overdue	8	--
Performance: % On Time	90%	--
Highest Possible Performance	90%	--
BsUFA Goal: On Time Target %	90%	--
Goal Met Status	**Goal Met**	**--**

† Not a performance goal for this fiscal year.

Table A- 38. Scheduling Meetings: BPD Type 2a

Scheduling Meetings: BPD Type 2a	FY 2022†	FY 2023
Total Submissions (Workload)	--	19
Pending Within Goal	--	0
On Time	--	14
Overdue	--	5
Performance: % On Time	--	74%
Highest Possible Performance	--	74%
BsUFA Goal: On Time Target %	--	50%
Goal Met Status	**--**	**Will Meet Goal**

† Not a performance goal for this fiscal year.

Table A- 39. Scheduling Meetings: BPD Type 2b

Scheduling Meetings: BPD Type 2b	FY 2022†	FY 2023
Total Submissions (Workload)	--	42
Pending Within Goal	--	1
On Time	--	37
Overdue	--	4
Performance: % On Time	--	90%
Highest Possible Performance	--	90%
BsUFA Goal: On Time Target %	--	90%
Goal Met Status	**--**	**Currently Meeting, Pending**

†Not a performance goal for this fiscal year.

Table A- 40. Scheduling Meetings: BPD Type 3

Scheduling Meetings: BPD Type 3	FY 2022	FY 2023
Total Submissions (Workload)	2	1
Pending Within Goal	0	0
On Time	2	1
Overdue	0	0
Performance: % On Time	100%	100%
Highest Possible Performance	100%	100%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Met**	**Will Meet Goal**

Table A- 41. Scheduling Meetings: BPD Type 4

Scheduling Meetings: BPD Type 4	FY 2022	FY 2023
Total Submissions (Workload)	13	23
Pending Within Goal	0	0
On Time	10	16
Overdue	3	7
Performance: % On Time	77%	70%
Highest Possible Performance	77%	70%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Not Met**	**Will Not Meet Goal**

Table A- 42. Written Response: Biosimilar Initial Advisory

Written Response: Biosimilar Initial Advisory	FY 2022	FY 2023
Total Submissions (Workload)	3	2
Pending Within Goal	0	0
On Time	3	2
Overdue	0	0
Performance: % On Time	100%	100%
Highest Possible Performance	100%	100%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Met**	**Will Meet Goal**

Table A- 43. Written Response: BPD Type 2

Written Response: BPD Type 2	FY 2022	FY 2023†
Total Submissions (Workload)	14	--
Pending Within Goal	0	--
On Time	13	--
Overdue	1	--
Performance: % On Time	93%	--
Highest Possible Performance	93%	--
BsUFA Goal: On Time Target %	90%	--
Goal Met Status	**Goal Met**	**--**

†Not a performance goal for this fiscal year.

Table A- 44. Written Response: BPD Type 2a

Written Response: BPD Type 2a	FY 2022†	FY 2023
Total Submissions (Workload)	--	16
Pending Within Goal	--	4
On Time	--	12
Overdue	--	0
Performance: % On Time	--	100%
Highest Possible Performance	--	100%
BsUFA Goal: On Time Target %	--	50%
Goal Met Status	**--**	**Will Meet Goal**

† Not a performance goal for this fiscal year.

Table A- 45. Written Response: BPD Type 2b

Written Response: BPD Type 2b	FY 2022†	FY 2023
Total Submissions (Workload)	--	8
Pending Within Goal	--	2
On Time	--	5
Overdue	--	1
Performance: % On Time	--	83%
Highest Possible Performance	--	88%
BsUFA Goal: On Time Target %	--	90%
Goal Met Status	**--**	**Will Not Meet Goal**

† Not a performance goal for this fiscal year.

Table A- 46. Preliminary Response: BPD Type 2

Preliminary Response: BPD Type 2	FY 2022	FY 2023†
Total Submissions (Workload)	76	--
Pending Within Goal	0	--
On Time	67	--
Overdue	9	--
Performance: % On Time	88%	--
Highest Possible Performance	88%	--
BsUFA Goal: On Time Target %	90%	--
Goal Met Status	**Goal Not Met**	**--**

† Not a performance goal for this fiscal year.

Table A- 47. Preliminary Response: BPD Type 2b

Preliminary Response: BPD Type 2b	FY 2022†	FY 2023
Total Submissions (Workload)	--	39
Pending Within Goal	--	8
On Time	--	27
Overdue	--	4*
Performance: % On Time	--	87%
Highest Possible Performance	--	90%
BsUFA Goal: On Time Target %	--	90%
Goal Met Status	**--**	**Currently Not Meeting, Pending**

* Includes one overdue pending submission.
† Not a performance goal for this fiscal year.

Table A- 48. Preliminary Response: BPD Type 3

Preliminary Response: BPD Type 3	FY 2022	FY 2023
Total Submissions (Workload)	2	1
Pending Within Goal	0	1
On Time	2	0
Overdue	0	0
Performance: % On Time	100%	--†
Highest Possible Performance	100%	100%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Met**	**Currently Meeting,**

† Performance cannot be calculated as all submissions are currently pending within goal.

Table A- 49. Meeting Minutes: All Meeting Types

Meeting Minutes: All Meeting Types	FY 2022	FY 2023
Total Submissions (Workload)	76	70
Pending Within Goal	0	17
On Time	71	47
Overdue	5	6
Performance: % On Time	93%	89%
Highest Possible Performance	93%	91%
BsUFA Goal: On Time Target %	90%	90%
Goal Met Status	**Goal Met**	**Currently Not Meeting, Pending**

Appendix B: 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,[4] 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

[4] 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.[5]

[5] 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.

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.

For additional information on performance goals, refer to the BsUFA III Commitment Letter.[6]

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

Appendix C: Analysis of Use of Funds

On September 30, 2022, FUFRA was signed into law. FUFRA reauthorized the user fee programs for prescription drugs, generic drugs, medical devices, and biosimilar biological products.

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

Table C-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 2023, 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 2023, 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 C- 1. Aggregate Filings and Approvals for FY 2023 of Original Biosimilar Applications and Category A-F Supplements

Application Type	Performance Goal: Act on 90 Percent Within	Filed in FY 2023*	Approved in FY 2023	On Time†	Overdue†	Percent on Time
Original Biosimilar Applications	10 months of the 60-day filing date	19	3	3	0	100%
Resubmitted Original Biosimilar Applications	6 months of the receipt date	12	2	2	0	100%
Original Category A Supplements	3 months of the receipt date	5	4	4	0	100%
Original Category B Supplements	4 months of the receipt date	1	1	1	0	100%
Original Category C Supplements	4 months of the receipt date	0	0	--	--	--
Original Category D Supplements	6 months of the receipt date	11	8	8	0	100%
Original Category E Supplements	10 months of the receipt date	0	0	--	--	--
Original Category F Supplements	10 months of the receipt date	2	0	--	--	--
Resubmitted Category A Supplements	3 months of the receipt date	0	0	--	--	--
Resubmitted Category B Supplements	4 months of the receipt date	0	0	--	--	--
Resubmitted Category C Supplements	4 months of the receipt date	0	0	--	--	--
Resubmitted Category D Supplements	6 months of the receipt date	0	0	--	--	--
Resubmitted Category E Supplements	6 months of the receipt date	0	0	--	--	--
Resubmitted Category F Supplements	6 months of the receipt date	0	0	--	--	--
Total		**50**	**18**	**18**	**0**	**--‡**

* 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.

† 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

Table C-2 addresses 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 2023 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 C- 2. FY 2023 Performance Enhancement Goals

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
Quarterly Hiring Reporting Q1 FY 2023	1/21/2023	Y	1/26/2023	https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-and-bsufa-quarterly-hiring-updates **Note:** Since the BsUFA III Commitment Letter does not specify a date for the quarterly hiring updates, FDA will not submit a corrective action for the Q1 commitment.
Quarterly Hiring Reporting Q2 FY 2023	4/21/2023	Y	4/10/2023	
Quarterly Hiring Reporting Q3 FY 2023	7/21/2023	Y	7/12/2023	
Publish Capacity Planning Implementation Plan	3/31/2023	Y	3/29/2023	https://www.fda.gov/industry/fda-user-fee-programs/resource-capacity-planning-and-modernized-time-reporting
Publish Five-Year Financial Plan	3/31/2023	N	4/18/2023	https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans
Conduct Public Meeting Financial Plan FY23	6/30/2023	Y	6/8/2023	https://www.fda.gov/drugs/news-events-human-drugs/2023-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act
Hiring BsUFA Drug Review Staff FY23	9/30/2023	N	-	
Publish Draft Supplements Guidance	9/30/2023	Y	8/11/2023	https://www.fda.gov/regulatory-information/search-fda-guidance-

				documents/classification-categories-certain-supplements-under-bsufa-iii
Publish Revised Draft Guidance on Changes to Meeting Management	9/30/2023	Y	8/11/2023	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-sponsors-or-applicants-bsufa-products-guidance-industry
Publish Draft Guidance on Labeling for Interchangeable Biosimilars	9/30/2023	Y	9/18/2023	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/labeling-biosimilar-and-interchangeable-biosimilar-products
Develop and Update Data and Tech Modernization Strategy FY23	9/30/2023	Y	9/19/2023	https://www.fda.gov/about-fda/office-digital-transformation/fda-information-technology-strategy-fy-2024-fy-2027
Share ESG Implementation Project Plan (BsUFA Continuous Engagement Meeting) FY23	9/30/2023	Y	9/19/2023	
Publish Draft Guidance on Alternative Tools to Assess Manufacturing Facilities	9/30/2023	Y	9/22/2023	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-tools-assessing-drug-manufacturing-facilities-identified-pending-applications
Implement WRO for Clarification	10/1/2022	Y	9/30/2022	
Establish BsUFA Regulatory Science Pilot Program	10/1/2022	Y	10/1/2022	
Establish Human Factors Validation Study Review Protocols	10/1/2022	Y	10/1/2022	
Implement New Review Goals for Supplements	10/1/2022	Y	10/1/2022	
Implement BPD Type 2A Meetings	10/1/2022	Y	10/1/2022	
Implement Changes to BIA Meetings	10/1/2022	Y	10/1/2022	
Enhance Inspection Communication for Applications	10/1/2022	Y	10/1/2022	

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

Table C-3 addresses 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 2022 updated performance results.

Table C- 3. FY 2022 Updated Performance Results

Cause or Trend	Impact on FDA's Commitments
• Small review performance cohort for original supplements with clinical data	• Because some review performance cohorts are small, a single missed goal had a large impact on goal performance. The original supplements with clinical data cohort had a total cohort of 16, and most of the cohort was not complete at the time preliminary results for FY 2022 were published.

Table C-4 represents FDA's FY 2023 preliminary performance results.

Table C- 4. FY 2023 Preliminary Performance Results

Cause or Trend	Impact on FDA's Commitments
• Small procedural and meeting goal cohorts for special protocol assessments and BPD Type 2b written responses	• Because the special protocol assessment and BPD Type 2b written response cohorts were small (four and eight, respectively), a single missed goal had a large impact on goal performance.
• Increasing resource-intensive workload across user fee programs repeatedly strained the same set of key staff within relevant offices/divisions	• For the missed goals for Human Factors Protocol Submission to INDs (respond within 60 days), response to BPD Type 2a meeting requests (respond within 21 days), BPD Type 4 meetings scheduling (scheduling within 60 days), and BPD Type 2b written responses (respond 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.

Appendix D: FY 2023 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 D-1 represents FDA's FY 2022 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 2022, then the Agency fully reported on it in the last fiscal year's report.[7]

Table D- 1. FY 2022 Review and Procedural and Processing Goal Performance Results (Updated)

Goal Type	Circumstances and Trends Impacting the Ability to Meet the Goal Date	Corrective Action Plan
Review Performance	• For original supplements with clinical data, the cohort was small, with 16 submissions received. FDA would miss the 90-percent performance goal even if only two submissions were not acted on within the goal time frame. No consistent primary factors were responsible for the four missed goals in this cohort.	• FDA continues to strive to meet all BsUFA review performance goals
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.	• FDA continues to strive to meet all BsUFA procedural and processing goals

Table D-2 relates to FDA's FY2023 preliminary performance results missed goals type(s), circumstances and trends impacting FDA's ability to meet the goal date, and the corrective action plan.

Table D- 2. FY 2023 Review and Procedural and Processing Goal Performance Results

Goal Type	Circumstances and Trends Impacting the Ability to Meet 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,

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

Table D-3 relates to FDA's FY2023 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 D- 3. FY 2023 Performance Enhancement Goal Performance Results

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Financial Planning	• Delays occurred because of a heavily manual financial reporting process that hindered performance, resulting in the late publication of the BsUFA Five-Year Financial Plan.	• FDA's Office of Financial Management, in collaboration with other FDA Centers/Offices, created a working group to review the content of the user fee financial reports and the five-year financial plan to streamline the documents, standardize the language, and improve the development process. In addition, in 2023, FDA has automated existing manual processes for generating the 5-year financial plans.
Hiring	• Some hiring managers were faced with difficulties in finding candidates with the specific specialty needed to conduct the work.	• CDER is partnering with the Office of Talent Solutions and hiring managers to expand its outreach capacity and recruitment strategies to mitigate the challenges faced with finding and selecting candidates.

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 2023 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 2023. This section also includes FDA's FY 2022 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 2022, then the Agency fully reported on it in the last fiscal year's report.

1. FY 2022 Updated Review Performance Results

Summary of Performance

FDA missed the review performance goal for original supplements with clinical data.

Justification

A single missed goal could have a large impact on review goal performance. For original supplements with clinical data, 16 submissions were received. FDA would miss the 90-percent performance goal even if only two submissions were not acted on within the goal time frame. No consistent primary factors were responsible for the four missed goals in this cohort.

FY 2023 Corrective Actions

FDA will continue to strive to meet all BsUFA review goals.

2. FY 2023 Review Goal Performance Results

Summary of Performance

FDA is currently meeting or has the potential to meet all review performance goals for FY 2023.

3. FY 2023 Procedural and Processing Performance Results

Summary of Performance FDA missed the following procedural notification and meeting management goals:

- Special Protocol Assessments (respond within 45 days)
- Human Factors Protocol Submissions to INDs (respond within 60 days)
- Meeting request response for BPD Type 2a meetings (respond within 21 days)
- Meeting scheduling for BPD Type 4 meetings (schedule within 60 days)
- Written response for BPD Type 2b meetings (respond within 90 days)

B. Justification

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. Also, 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.

FY 2024 Corrective Actions

FDA continues to assess ways to handle the procedural goals and meeting requests, as well as the increasing review workload, 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 2023. 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 Planning

Summary of Performance

FDA missed the goal to publish a BsUFA Five-Year Financial Plan. The financial plan, due by March 31, 2023, was published on April 18, 2023.

Justification

Delays occurred because of a heavily manual financial reporting process that hindered performance, resulting in the late publication of the BsUFA 5-Year Financial Plan.

FY 2024 Corrective Actions

FDA's Office of Financial Management, in collaboration with the other FDA Centers/Offices, created a working group to review the content of the user fee financial reports and the five-year financial plans to streamline the documents, standardize the language, and improve the development process. In addition, in FY24, FDA automated existing manual processes for generating the five-year financial plans. The automated platform can pull from multiple data sources and handle complex calculations, thereby, reducing manual entry, minimizing errors, and increasing efficiency.

2. Hiring

Summary of Performance

FDA missed the BsUFA III goal for hiring in FY 2023. As of September 29, 2023, seven of the remaining 14 FTEs were hired.

Justification

Of the seven remaining positions, four had candidates identified as of September 29, 2023. Of those four positions, one candidate was awaiting a final offer, and the other three were awaiting tentative offers.

As for the positions that did not have candidates identified, some hiring managers were faced with difficulties in finding candidates with the specific specialty needed to conduct the work.

FY 2024 Corrective Actions

CDER is partnering with the Office of Talent Solutions and hiring managers to expand CDER's outreach capacity and recruitment strategies to mitigate the challenges faced with finding and selecting candidates. FDA will fill the remaining BsUFA III positions allocated for FY 2023 and will continue to track hiring progress until all 14 are on board.

This report was prepared by FDA's Office of Planning, Evaluation, and Risk Management 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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