Performance Report to Congress

Biosimilar User Fee Act

FY 2022

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 authorization of BsUFA, FDA developed enhancements for the second authorization of BsUFA (BsUFA II) 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) 2018 to 2022 period, detailed in the BsUFA II 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 10th year of the BsUFA program and the fifth year of BsUFA II. The report presents FDA's final performance results in meeting BsUFA goals and commitments for FY 2021 and FDA's preliminary performance results for FY 2022.

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 II Commitment Letter. Additional information regarding corrective actions for missed goals can be found in Appendix D: FY 2022 Corrective Action Report. Key highlights for the BsUFA program include the following:

- Of the 28 BsUFA goal categories, 27 applied to FY 2021 biosimilar submissions. FDA met or exceeded 15 of these 27 goals.

- FDA has the potential to meet or exceed 17 of the 25 goals that apply to the FY 2022 cohort once these actions are completed.

[1] Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, available at https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf.

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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
FDARA	FDA Reauthorization Act of 2017
FTE	Full-time Equivalents
FY	Fiscal Year (October 1 to September 30)
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 reauthorized 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 (FDARA). BsUFA 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 biosimilar biological product (also referred to as "biosimilar") submissions 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 2021 and FDA's preliminary performance results for FY 2022. These data represent FDA's performance on submissions received and actions taken as of September 30, 2022. Final FDA performance results for FY 2022 submissions will be presented in the FY 2023 BsUFA performance report and will include final actions for submissions still pending within the BsUFA goal date as of September 30, 2022. 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, 2022.

- 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 applications reviewed under the program (see the BsUFA II Commitment Letter[1] 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.

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.

Additional definitions are included in **Appendix B** of this report.

[1] Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, available at https://www.fda.gov/media/100573/download.

II. BsUFA Performance Goals and Commitments

The tables below present the goal timelines and the percentage of submissions that FDA committed to review within those goal timelines for FY 2018 through FY 2022. 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 2018 to FY 2022

BsUFA Submission Type	Goal: Act on Within	FY 18	FY 19	FY 20	FY 21	FY 22
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 Supplements with Clinical Data	10 months	90%	90%	90%	90%	90%
Resubmitted Supplements with Clinical Data	6 months	90%	90%	90%	90%	90%
Manufacturing Supplements Requiring Prior Approval	4 months	70%	75%	80%	85%	90%
Manufacturing Supplements Not Requiring Prior Approval	6 months	90%	90%	90%	90%	90%

Table 2. FDA's Procedural and Meeting Goals from FY 2018 to FY 2022

BsUFA Submission Type	Goal	FY 18	FY 19	FY 20	FY 21	FY 22
Procedural Notifications						
Notification of Issues Identified During the Filing Review for Supplements with Clinical	Notify within 74 days	90%	90%	90%	90%	90%
Notification of Planned Review Timeline for Supplements with Clinical Data	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%

BsUFA Submission Type	Goal	FY 18	FY 19	FY 20	FY 21	FY 22
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 2	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 2	Schedule within 90 days	80%	80%	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 2	Respond within 90 days	80%	80%	90%	90%	90%
Preliminary Responses: BPD Type 2	Issue no later than 5 days prior to meeting date	70%	75%	80%	85%	90%
Preliminary Responses: BPD Type 3	Issue no later than 5 days prior to meeting date	90%	90%	90%	90%	90%
Meeting Minutes: All Meeting Types	Issue within 30 days after meeting date	90%	90%	90%	90%	90%

III. FY 2021 Final BsUFA Performance Summary

The FY 2021 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, 27 applied to FY 2021 biosimilar submissions. FDA met or exceeded 15 of these 27 goals. No submissions were received for 1 of the 28 BsUFA goal categories that are indicated with an "NA" in the tables below.

Table 3. FY 2021 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	9 of 10	90%	90%	Yes
Resubmitted Original Biosimilar Applications	6 months	5 of 5	90%	100%	Yes
Original Supplements with Clinical Data	10 months	9 of 10	90%	90%	Yes
Resubmitted Supplements with Clinical Data	6 months	1 of 1	90%	100%	Yes
Manufacturing Supplements Requiring Prior Approval	4 months	47 of 50	85%	94%	Yes
Manufacturing Supplements Not Requiring Prior Approval	6 months	40 of 40	90%	100%	Yes

Table 4. FY 2021 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	7 of 7	90%	100%	Yes
Notification of Planned Review Timeline for Supplements with Clinical Data	Notify within 74 days	7 of 7	90%	100%	Yes
Proprietary Name Submitted During BPD Phase	Review and respond within 180 days	7 of 8	90%	88%	No
Proprietary Name Submitted During Application Review	Review and respond within 90 days	14 of 15	90%	93%	Yes

BsUFA Submission Type	Goal	On Time	Performance Goal	Percent on Time	Goal Met
Procedural Responses					
Major Dispute Resolution	Respond within 30 days	0 of 0	90%	NA*	NA*
Responses to Clinical Holds	Respond within 30 days	2 of 2	90%	100%	Yes
Special Protocol Assessments	Respond within 45 days	1 of 1	90%	100%	Yes
Meeting Management					
Meeting Requests: BIA	Respond within 21 days	5 of 6	90%	83%	No
Meeting Requests: BPD Type 1	Respond within 14 days	4 of 4	90%	100%	Yes
Meeting Requests: BPD Type 2	Respond within 21 days	75 of 90	90%	83%	No
Meeting Requests: BPD Type 3	Respond within 21 days	6 of 7	90%	86%	No
Meeting Requests: BPD Type 4	Respond within 21 days	8 of 10	90%	80%	No
Scheduling Meetings: BIA	Schedule within 75 days	3 of 3	90%	100%	Yes
Scheduling Meetings: BPD Type 1	Schedule within 30 days	3 of 4	90%	75%	No
Scheduling Meetings: BPD Type 2	Schedule within 90 days	54 of 64	90%	84%	No
Scheduling Meetings: BPD Type 3	Schedule within 120 days	5 of 6	90%	83%	No
Scheduling Meetings: BPD Type 4	Schedule within 60 days	7 of 10	90%	70%	No
Written Response: BIA	Respond within 75 days	2 of 2	90%	100%	Yes
Written Response: BPD Type 2	Respond within 90 days	21 of 23	90%	91%	Yes
Preliminary Responses: BPD Type 2	Issue no later than 5 days prior to meeting date	52 of 64	85%	81%	No
Preliminary Responses: BPD Type 3	Issue no later than 5 days prior to meeting date	5 of 6	90%	83%	No
Meeting Minutes: All Meeting Types	Issue within 30 days after meeting date	58 of 68	90%	85%	No

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

IV. FY 2022 Preliminary BsUFA Performance Summary

FY 2022 BsUFA performance results are presented in the tables below.

- The *Actions Completed* column shows how much of the cohort has been acted on by presenting the number of submissions that had actions taken in FY 2022 or were overdue as of September 30, 2022, 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, 2022. Actions that were pending and not yet past the goal date as of September 30, 2022, 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 17 of the 25 goals that apply to the FY 2022 cohort once these actions are completed.

Table 5. FY 2022 Preliminary Review Goal Performance Results

BsUFA Submission Type	Actions Completed	Goal: Act on Within	Performance Goal	Percent on Time	Highest Possible Performance
Biosimilar Applications and Supplements					
Original Biosimilar Product Applications	0 of 10 complete	10 months from 60-day filing date	90%	--	100%
Resubmitted Original Biosimilar Applications	2 of 7 complete	6 months	90%	100%	100%
Original Supplements with Clinical Data	2 of 16 complete	10 months	90%	100%	100%
Resubmitted Supplements with Clinical Data	0 of 0 complete	6 months	90%	NA*	NA*
Manufacturing Supplements Requiring Prior Approval	26 of 35 complete	4 months	90%	88%	91%
Manufacturing Supplements Not Requiring Prior Approval	16 of 38 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 2022 Preliminary Procedural and Meeting Goal Performance Results

BsUFA Submission Type	Actions Completed	Goal	Performance Goal	Percent on Time	Highest Possible Performance
Procedural Notifications					
Notification of Issues Identified During the Filing Review for Supplements with Clinical Data	6 of 8 complete	Notify within 74 days	90%	100%	100%
Notification of Planned Review Timeline for Supplements with Clinical Data	6 of 8 complete	Notify within 74 days	90%	100%	100%
Proprietary Name Submitted During BPD Phase	7 of 13 complete	Review and respond within 180 days	90%	14%	54%
Proprietary Name Submitted During Application Review	20 of 24 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 3 complete	Respond within 45 days	90%	100%	100%
Meeting Management					
Meeting Requests: BIA	9 of 9 complete	Respond within 21 days	90%	100%	100%
Meeting Requests: BPD Type 1**	14 of 15 complete	Respond within 14 days	90%	86%	87%
Meeting Requests: BPD Type 2	93 of 97 complete	Respond within 21 days	90%	87%	88%
Meeting Requests: BPD Type 3	2 of 2 complete	Respond within 21 days	90%	100%	100%
Meeting Requests: BPD Type 4	13 of 13 complete	Respond within 21 days	90%	85%	85%
Scheduling Meetings: BIA	4 of 5 complete	Schedule within 75 days	90%	75%	80%
Scheduling Meetings: BPD Type 1**	13 of 15 complete	Schedule within 30 days	90%	69%	73%

BsUFA Submission Type	Actions Completed	Goal	Performance Goal	Percent on Time	Highest Possible Performance
Scheduling Meetings: BPD Type 2	75 of 77 complete	Schedule within 90 days	90%	89%	90%
Scheduling Meetings: BPD Type 3	2 of 2 complete	Schedule within 120 days	90%	100%	100%
Scheduling Meetings: BPD Type 4	13 of 13 complete	Schedule within 60 days	90%	77%	77%
Written Response: BIA	2 of 2 complete	Respond within 75 days	90%	100%	100%
Written Response: BPD Type 2	12 of 14 complete	Respond within 90 days	90%	92%	93%
Preliminary Responses: BPD Type 2	63 of 73 complete	Issue no later than 5 days prior to meeting date	90%	84%	86%
Preliminary Responses: BPD Type 3	1 of 2 complete	Issue no later than 5 days prior to meeting date	90%	100%	100%
Meeting Minutes: All Meeting Types	48 of 81 complete	Issue within 30 days after meeting date	90%	96%	98%

* 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 two 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 2023 BsUFA Performance Report.

V. BsUFA Workload

Workload: FY 2018 to FY 2022

The tables below present the workload numbers from FY 2018 to FY 2022.

Table 7. Review Workload

BsUFA Workload	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Biosimilar Applications and Supplements					
Original Biosimilar Product Applications	6	7	8	10*	10
Resubmitted Original Biosimilar Applications	6	4	1	5	7
Original Supplements with Clinical Data	3	12	2	10*	16
Resubmitted Supplements with Clinical Data	0	0	1	1	0
Manufacturing Supplements Requiring Prior Approval	6	22	43	50*	35
Manufacturing Supplements Not Requiring Prior Approval	19	28	31	40*	38

* FY 2021 numbers were changed to reflect updates to the data presented in the FY 2021 BsUFA Performance Report.

Table 8. Procedural and Meeting Workload

BsUFA Workload	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Procedural Notifications					
Notification of Issues Identified During the Filing Review for Supplements with Clinical Data	1	7	1	7*	8
Notification of Planned Review Timeline for Supplements with Clinical Data	1	6	1	7*	8
Proprietary Name Submitted During BPD Phase	10	3	6	8	13
Proprietary Name Submitted During Application Review	15	15	10	15	24
Procedural Responses					
Major Dispute Resolution	0	0	0	0	0
Responses to Clinical Holds	0	1	0	2	0
Special Protocol Assessments	3	2	2	1	3
Meeting Management					
Meeting Requests: BIA	12	11	8	6	9
Meeting Requests: BPD Type 1	6	9	6	4	15**
Meeting Requests: BPD Type 2	47	77	67	90*	97
Meeting Requests: BPD Type 3	1	9	4	7	2
Meeting Requests: BPD Type 4	6	8	8	10*	13
Scheduling Meetings: BIA	5	7	4	3	5

BsUFA Workload	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Scheduling Meetings: BPD Type 1	5	8	6	4	15**
Scheduling Meetings: BPD Type 2	31	55	44	64*	77
Scheduling Meetings: BPD Type 3	1	9	3	6	2
Scheduling Meetings: BPD Type 4	6	7	8	10*	13
Written Response: BIA	1	0	2	2	2
Written Response: BPD Type 2	10	16	21	23*	14
Preliminary Responses: BPD Type 2	30	54	44	64*	73
Preliminary Responses: BPD Type 3	1	9	3	6	2
Meeting Minutes: All Meeting Types	43	71	52	68	81

* FY 2021 numbers were changed to reflect updates to the data presented in the FY 2021 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 two 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 2023 BsUFA Performance Report.

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, 2022, 64 351(k) applications were accepted for filing by FDA.

As of September 30, 2022, 61 percent of the 351(k) applications that have been filed by FDA have been approved.

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 903(d)(2) of FDARA added section 744I(a)(2) of the FD&C Act, which requires that beginning in FY 2018, FDA report the following:

- 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 and there are two supplements that have not received an action from the FY 2021 or earlier cohorts.

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

Application Type	FY 2022 Filed*/Approved as of 9/30/2022
Original Biosimilar Product Applications	10 / 0
Resubmitted Original Biosimilar Product Applications	7 / 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

FDARA amended the FD&C Act to require the reporting of certain information relating to BsUFA program changes in the annual performance report starting with FY 2020.

Specifically, section 903(d)(2) of FDARA added section 744I(a)(4) of the FD&C Act, which requires the annual BsUFA performance report to include the following:

(A) data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017 and the number of full-time equivalents 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 drivers of such changes; and

(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.

The information below fulfills these reporting requirements.

A. Changes in the number of full-time equivalents (FTEs) hired as agreed upon in the BsUFA Commitment Letter and the number of FTEs funded by budget authority at FDA by division within CDER, CBER, the Office of Regulatory Affairs (ORA), and the Office of the Commissioner (OC)

This section addresses the requirement to provide data, analysis, and discussion of the changes in the number of FTEs hired as agreed upon in the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017 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 FTEs hired as agreed upon in the BsUFA II Commitment Letter

The BsUFA II Commitment Letter states that "FDA will target hiring 15 FTE[s] in FY 2018, to enhance capacity for biosimilar guidance development, reviewer training, and timely

communication." FDA completed these hires in FY 2020. The data in the following table show the changes from FY 2021 to FY 2022 in the number of FTEs hired as agreed upon in the BsUFA II Commitment Letter.

Because FDA completed its target hiring of 15 FTEs in FY 2020, FDA did not need to hire additional FTEs in FY 2021 or FY 2022 to fulfill that hiring target. FDA thus did not hire FTEs pursuant to the BsUFA II Commitment Letter in FY 2021 or FY 2022; accordingly, there was no change in the hiring of such FTEs from FY 2021 to FY 2022.

Table 10. Number of FTEs Hired as Agreed Upon in the BsUFA II Commitment Letter

Center	Number of FTEs Hired in FY 2021	Number of FTEs Hired in FY 2022	Change in Number of FTEs Hired
CDER	0	0	0
CBER	0	0	0
ORA	0	0	0
OC	0	0	0

2. Changes in the number of FTEs funded by budget authority at FDA by division within CDER, CBER, ORA, and OC

The data in the table below show the change from FY 2021 to FY 2022 in the number of FTEs funded by budget authority at FDA by each division within CDER, CBER, ORA and OC. This table reflects the number of FTEs funded by budget authority for the BsUFA II 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. Data for FY 2022 and the previous fiscal year, FY 2021, are presented and compared to show the change in the number of FTEs over the last two fiscal years committed to BsUFA work. The number of FTEs funded by budget authority for FY 2021 are those FTEs as of September 30, 2021. The number of FTEs funded by budget authority for FY 2022 are those FTEs as of September 30, 2022.

Overall, FDA reported an increase of approximately 11 FTEs funded by budget authority in FY 2022 compared to FY 2021. The increase in FTEs funded by budget authority was attributable to increases in program workload compared to FY 2021.

Table 11. Number of FTEs Funded by Budget Authority

Center and Office	Number of BsUFA Program FTEs Funded by Budget Authority*		Change in Number of BsUFA Program FTEs Funded by Budget Authority
	FY 2021	FY 2022	
CDER			
Office of Communications	0.9	1.2	0.3
Office of Compliance	0.6	1.5	0.9
Office of the Center Director	1.0	1.2	0.2
Office of Executive Programs	0.7	1.4	0.7
Office of Generic Drugs	0.1	0.0	-0.1
Office of Medical Policy	0.2	0.5	0.3
Office of Management	2.4	2.4	0.0
Office of New Drugs	10.2	15.7	5.5
Office of Pharmaceutical Quality	18.8	17.9	-0.9
Office of Regulatory Policy	1.6	0.0	-1.6
Office of Surveillance and Epidemiology	3.3	6.0	2.7
Office of Strategic Programs	1.4	1.1	-0.3
Office of Translational Sciences	6.8	6.4	-0.4
Other Offices	0.2	0.0	-0.2
Working Capital Fund (WCF)	2.5	2.5	0.0
CBER			
Office of Biostatistics and Epidemiology	0.0	0.0	0.0
Office of Blood Research and Review	0.0	0.0	0.0
Office of Compliance and Biologics Quality	0.1	0.3	0.2
Office of Tissues and Advanced Therapies	0.1	0.3	0.2

Center and Office	Number of BsUFA Program FTEs Funded by Budget Authority*		Change in Number of BsUFA Program FTEs Funded by Budget Authority
	FY 2021	FY 2022	
Office of Vaccines Research and Review	0.0	0.3	0.3
Office of Communication Outreach and Development	0.0	0.1	0.1
Office of the Center Director	0.2	0.2	0.0
Office of Management	0.1	0.2	0.1
Office of Regulatory Operations	N/A	0.1	0.1
WCF	0.0	0.0	0.0
OC			
Office of the Chief Counsel	0.3	1.1	0.8
Office of Clinical Policy and Programs	0.0	0.0	0.0
Office of Operations	1.0	2.6	1.6
Office of Policy, Legislation, and International Affairs	0.1	0.9	0.8
Office of Information Management and Technology	0.2	0.0	-0.2
WCF	0.4	0.5	0.1
ORA			
WCF	0.4	0.4	0.0

* 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.

A reorganization in CBER created this new office, which was previously a part of the Office of the Center Director.

B. Changes in the fee revenue amounts and costs for the review process

Section 903(d)(2) of FDARA added section 744I(a)(4) of the FD&C Act, which 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. Accordingly, the table below provides data for the BsUFA fee revenue amounts and process costs for FY 2021 and FY 2022, as well as the changes in these amounts from FY 2021 to FY 2022. 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 2022) and prior fiscal year (FY 2021).

The process for setting the annual target revenue is set forth in the statute. For FY 2022, the base revenue amount is the FY 2021 inflation adjusted fee revenue amount of $42,493,066. The FY 2022 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 $3,336,686, an amount equivalent to 4 weeks of FY 2022 operations. This resulted in a target revenue amount of $40,040,000 (rounded to the nearest thousand) for FY 2022. In FY 2022, FDA had net collections of $43 million in BsUFA fees, spent $46 million in user fees for the BsUFA program, and carried forward a cumulative balance of $43 million for future fiscal years. Detailed financial information for the BsUFA user fee program can be found in the FY 2022 BsUFA financial report.

In FY 2022, BsUFA obligations increased approximately $13 million from FY 2021. The increase in BsUFA fee fund obligations was largely attributable to investments in the BsUFA regulatory science program.

Table 12. Changes in the Fee Revenue Amounts and Review Process Costs

Fiscal Year	FY 2021	FY 2022	Change from FY 2021 to FY 2022
Net Fiscal Year Collections	$42,705,959	$43,106,548	+1%
Review Process Cost	$55,928,075	$68,521,689	+23%

C. Number of employees for whom time reporting is required

Section 903(d)(2) of FDARA added section 744I(a)(4) of the FD&C Act, which 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, the table below provides the number of employees within CDER, CBER, ORA, and OC who are required to report their time and those who are not required to report their time as of September 30, 2022.

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 2022

Center	FTEs for Which Time Reporting Is Required	FTEs for Which Time Reporting Is Not Required
CDER	5,430	12
CBER	1,232	5
ORA	4,422	280
OC	55	2,632

Appendix A: Performance Calculations

The following tables detail the final performance for FY 2021 and preliminary performance for the FY 2022 cohort of submissions. These data include the number of submissions reviewed on time (acted on by the BsUFA goal date) or overdue (acted on past the goal date or pending past the goal date) and the percent on time (final performance with no actions pending within the BsUFA goal date for FY 2021 and current performance for FY 2022). 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. The FY 2021 performance data presented here have been updated from the preliminary performance information reported in the FY 2021 BsUFA performance report.

A. Review Goal Performance

Biosimilar Applications and Supplements

Original Biosimilar Product Applications	FY 2021	FY 2022
Total Filed Submissions (Workload)	**10**	**10**
Pending Within Goal	0	10
On Time	9	0
Overdue	1	0
Performance: % On Time	**90%**	**--**
Highest Possible Performance	**90%**	**100%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Met**	**Currently Meeting, Pending**

Resubmitted Original Biosimilar Applications	FY 2021	FY 2022
Total Submissions (Workload)	**5**	**7**
Pending Within Goal	0	5
On Time	5	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**	**Currently Meeting, Pending**

Original Supplements with Clinical Data	FY 2021	FY 2022
Total Filed Submissions (Workload)	**10**	**16**
Pending Within Goal	0	14
On Time	9	2
Overdue	1	0
Performance: % On Time	**90%**	**100%**
Highest Possible Performance	**90%**	**100%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Met**	**Currently Meeting, Pending**

Resubmitted Supplements with Clinical Data	FY 2021	FY 2022
Total Submissions (Workload)	**1**	**0**
Pending Within Goal	0	0
On Time	1	0
Overdue	0	0
Performance: % On Time	**100%**	**NA**
Highest Possible Performance	**100%**	**NA**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Met**	**NA**

Manufacturing Supplements Requiring Prior Approval	FY 2021	FY 2022
Total Filed Submissions (Workload)	**50**	**35**
Pending Within Goal	0	9
On Time	47	23
Overdue	3	3*
Performance: % On Time	**94%**	**88%**
Highest Possible Performance	**94%**	**91%**
BsUFA Goal: On Time Target %	**85%**	**90%**
Goal Met Status	**Goal Met**	**Currently Not Meeting, Pending**

* Includes one overdue pending submission.

Manufacturing Supplements Not Requiring Prior Approval	FY 2021	FY 2022
Total Filed Submissions (Workload)	**40**	**38**
Pending Within Goal	0	22
On Time	40	16
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**	**Currently Meeting, Pending**

B. Procedural and Meeting Goal Performance

Procedural Notifications

Notification of Issues Identified During the Filing Review for Supplements with Clinical Data	FY 2021	FY 2022
Total Filed Submissions (Workload)	**7**	**8**
Pending Within Goal	0	2
On Time	7	6
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**	**Currently Meeting, Pending**

Notification of Planned Review Timeline for Supplements with Clinical Data	FY 2021	FY 2022
Total Filed Submissions (Workload)	**7**	**8**
Pending*	0	2
In 74-Day Letter	7	6
Not in 74-Day Letter	0	0
Performance: % On Time	**100%**	**100%**
Highest Possible Performance	**100%**	**100%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Met**	**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.

Proprietary Name Submitted During BPD Phase	FY 2021	FY 2022
Total Submissions (Workload)	**8**	**13**
Pending Within Goal	0	6
On Time	7	1
Overdue	1	6*
Performance: % On Time	**88%**	**14%**
Highest Possible Performance	**88%**	**54%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Not Met**	**Will Not Meet Goal**

* Includes five overdue pending submissions.

Proprietary Name Submitted During Application Review	FY 2021	FY 2022
Total Submissions (Workload)	**15**	**24**
Pending Within Goal	0	4
On Time	14	20
Overdue	1	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**

Procedural Responses

Major Dispute Resolution	FY 2021	FY 2022
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**

Responses to Clinical Holds	FY 2021	FY 2022
Total Submissions (Workload)	**2**	**0**
Pending Within Goal	0	0
On Time	2	0
Overdue	0	0
Performance: % On Time	**100%**	**NA**
Highest Possible Performance	**100%**	**NA**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Met**	**NA**

Special Protocol Assessments*	FY 2021	FY 2022
Total Submissions (Workload)	**1**	**3**
Pending Within Goal	0	0
On Time	1	3
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**

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

Meeting Management[2]

Responses to Meeting Requests: Biosimilar Initial Advisory	FY 2021	FY 2022
Total Submissions (Workload)	**6**	**9**
Pending Within Goal	0	0
On Time	5	9
Overdue	1	0
Performance: % On Time	**83%**	**100%**
Highest Possible Performance	**83%**	**100%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Not Met**	**Will Meet Goal**

[2] 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.

Responses to Meeting Requests: BPD Type 1	FY 2021	FY 2022
Total Submissions (Workload)	**4**	**15**
Pending Within Goal	0	1
On Time	4	12
Overdue	0	2*
Performance: % On Time	**100%**	**86%**
Highest Possible Performance	**100%**	**87%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Met**	**Will Not Meet Goal**

* Includes one overdue pending submission.

Responses to Meeting Requests: BPD Type 2	FY 2021	FY 2022
Total Submissions (Workload)	**90**	**97**
Pending Within Goal	0	4
On Time	75	81
Overdue	15	12*
Performance: % On Time	**83%**	**87%**
Highest Possible Performance	**83%**	**88%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Not Met**	**Will Not Meet Goal**

* Includes one overdue pending submission.

Responses to Meeting Requests: BPD Type 3	FY 2021	FY 2022
Total Submissions (Workload)	**7**	**2**
Pending Within Goal	0	0
On Time	6	2
Overdue	1	0
Performance: % On Time	**86%**	**100%**
Highest Possible Performance	**86%**	**100%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Not Met**	**Will Meet Goal**

Responses to Meeting Requests: BPD Type 4	FY 2021	FY 2022
Total Submissions (Workload)	**10**	**13**
Pending Within Goal	0	0
On Time	8	11
Overdue	2	2
Performance: % On Time	**80%**	**85%**
Highest Possible Performance	**80%**	**85%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Not Met**	**Will Not Meet Goal**

Scheduling Meetings: Biosimilar Initial Advisory	FY 2021	FY 2022
Total Submissions (Workload)	**3**	**5**
Pending Within Goal	0	1
On Time	3	3
Overdue	0	1
Performance: % On Time	**100%**	**75%**
Highest Possible Performance	**100%**	**80%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Met**	**Will Not Meet Goal**

Scheduling Meetings: BPD Type 1	FY 2021	FY 2022
Total Submissions (Workload)	**4**	**15**
Pending Within Goal	0	2
On Time	3	9
Overdue	1	4
Performance: % On Time	**75%**	**69%**
Highest Possible Performance	**75%**	**73%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Not Met**	**Will Not Meet Goal**

Scheduling Meetings: BPD Type 2	FY 2021	FY 2022
Total Submissions (Workload)	**64**	**77**
Pending Within Goal	0	2
On Time	54	67
Overdue	10	8*
Performance: % On Time	**84%**	**89%**
Highest Possible Performance	**84%**	**90%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Not Met**	**Currently Not Meeting, Pending**

* Includes one overdue pending submission.

Scheduling Meetings: BPD Type 3	FY 2021	FY 2022
Total Submissions (Workload)	**6**	**2**
Pending Within Goal	0	0
On Time	5	2
Overdue	1	0
Performance: % On Time	**83%**	**100%**
Highest Possible Performance	**83%**	**100%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Not Met**	**Will Meet Goal**

Scheduling Meetings: BPD Type 4	FY 2021	FY 2022
Total Submissions (Workload)	**10**	**13**
Pending Within Goal	0	0
On Time	7	10
Overdue	3	3
Performance: % On Time	**70%**	**77%**
Highest Possible Performance	**70%**	**77%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Not Met**	**Will Not Meet Goal**

Written Response: Biosimilar Initial Advisory	FY 2021	FY 2022
Total Submissions (Workload)	**2**	**2**
Pending Within Goal	0	0
On Time	2	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**

Written Response: BPD Type 2	FY 2021	FY 2022
Total Submissions (Workload)	**23**	**14**
Pending Within Goal	0	2
On Time	21	11
Overdue	2	1
Performance: % On Time	**91%**	**92%**
Highest Possible Performance	**91%**	**93%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Met**	**Currently Meeting, Pending**

Preliminary Response: BPD Type 2	FY 2021	FY 2022
Total Submissions (Workload)	**64**	**73**
Pending Within Goal	0	10
On Time	52	53
Overdue	12	10*
Performance: % On Time	**81%**	**84%**
Highest Possible Performance	**81%**	**86%**
BsUFA Goal: On Time Target %	**85%**	**90%**
Goal Met Status	**Goal Not Met**	**Will Not Meet Goal**

* Includes one overdue pending submission

Preliminary Response: BPD Type 3	FY 2021	FY 2022
Total Submissions (Workload)	**6**	**2**
Pending Within Goal	0	1
On Time	5	1
Overdue	1	0
Performance: % On Time	**83%**	**100%**
Highest Possible Performance	**83%**	**100%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Not Met**	**Currently Meeting, Pending**

Meeting Minutes: All Meeting Types	FY 2021	FY 2022
Total Submissions (Workload)	**68**	**81**
Pending Within Goal	0	33
On Time	58	46
Overdue	10	2*
Performance: % On Time	**85%**	**96%**
Highest Possible Performance	**85%**	**98%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Not Met**	**Currently Meeting, Pending**

* Includes one overdue pending submission.

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,[3] 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

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.

[3] 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.

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. Such term 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. Such term may include substantive review of summary data but does not include review of full study reports.

VII. A BPD Type 3 Meeting is an in-depth data review and advice meeting regarding an ongoing biosimilar biological product development program. Such term 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.

VIII. 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 II Commitment Letter.[4]

[4] Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, available at https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf.

Appendix C: Analysis of Use of Funds

On August 18, 2017, FDARA was signed into law. FDARA amended the FD&C Act to revise and extend the user fee programs for prescription drugs, generic drugs, medical devices, and biosimilar biological products, and for other purposes.

A. Original Biosimilar Applications and Supplements with Clinical Data Aggregate Filings and Approvals

The following table addresses section 744I(a)(5)(A) of the FD&C Act, added by section 904(d) of FDARA, 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 401(b) of the Biosimilar User Fee Amendments of 2017 for the applicable fiscal year.

Approval data represent all approvals of biosimilar biological product applications and supplements with clinical data that occurred during FY 2022, regardless of when the application was received. Filing data represent filings of biosimilar biological product applications and supplements with clinical data that occurred during FY 2022, 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 multiple cycle approvals as well. 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. Original Biosimilar Applications and Supplements with Clinical Data Aggregate Filings and Approvals for FY 2022

Application Type	Performance Goal: Act on 90 Percent Within	Filed in FY 2022*	Approved in FY 2022	On Time	Overdue	Percent on Time
Original Biosimilar Applications	10 months of the 60-day filing date	10	6	5	1	83%
Resubmitted Original Biosimilar Applications	6 months of the receipt date	7	2	2	0	100%
Original Supplements with Clinical Data	10 months of the receipt date	16	11	11	0	100%
Resubmitted Supplements with Clinical Data	6 months of the receipt date	0	0	--	--	--
Total		**33**	**19**	**18**	**1**	**--‡**

* 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

The following table addresses section 744I(a)(5)(B) of the FD&C Act, added by section 904(d) of FDARA, 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 401(b) of the Biosimilar User Fee Amendments of 2017 for the applicable fiscal year. A link to each performance enhancement goal completed under BsUFA II can be found on FDA's website located at https://www.fda.gov/industry/biosimilar-user-fee-amendments/completed-bsufa-ii-deliverables.

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

The table below represents FDA's FY 2022 performance.

Table C-2. FY 2022 Performance Enhancement Goals

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
Final Assessment for Hiring and Retention	12/31/2021	Y	12/10/2021	FDA Final Hiring and Retention Assessment Final Report (see https://www.fda.gov/media/154873/download)
Public Meeting for Final Assessment for Hiring and Retention	3/30/2022	Y	3/15/2022	FDA Hiring and Retention Final Assessment Public Meeting (see https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-pdufa-hiring-and-retention-final-assessment-public-meeting-03152022)
FY 2022 Annual Update to Five-Year Financial Plan	3/31/2022	Y	3/30/2022	User Fee Five-Year Financial Plans (see https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans)
Final Assessment of BsUFA Program	6/30/2022	Y	2/21/2022	BsUFA II: Assessment of the Program for Enhanced Review Transparency and Communication in the Biosimilar User Fee Act (see https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-ii-assessment-program-enhanced-review-transparency-and-communication-biosimilar-user-fee-act)
FY 2022 Financial Public Meeting	6/30/2022	Y	6/7/2022	2022 Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments (see https://www.fda.gov/drugs/news-events-human-drugs/2022-financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act)
Public Meeting for Final Assessment of BsUFA Program	9/30/2022	Y	3/22/2022	Public Meeting: Final Assessment of the Program for Enhanced Review Transparency and Communication in the Biosimilar User Fee Act (see https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-final-assessment-program-enhanced-review-transparency-and-communication-biosimilar)
Reduce the Carryover Balance (to no greater than 21 weeks of the FY 2022 target revenue)	9/30/2022	N	N/A	As set forth in the BsUFA II Commitment Letter, FDA will (1) outline its plan to reduce the carryover balance to no greater than 21 weeks in the FY 2022 BsUFA financial report and (2) update the BsUFA five-year financial plan.

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

The following table addresses section 744I(a)(5)(C) of the FD&C Act, added by section 904(d) of FDARA, 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 401(b) of the Biosimilar User Fee Amendments of 2017.

In addition to the causes and trends initially identified in last year's report, the table below represents FDA's FY 2021 updated performance results.

Table C-3. FY 2021 Updated Performance Results

Cause or Trend	Impact on FDA's Commitments
Procedural cohorts are small	• Because procedural goal cohorts are small, a single missed goal has a large impact on procedural goal performance. For the procedural notification goal for proprietary name submitted during BPD phase, because there were fewer than 10 notifications, FDA would miss the 90 percent performance goal even if only one notification is not acted on within the goal time frame.

The table below represents FDA's FY 2022 preliminary performance results.

Table C-4. FY 2022 Preliminary Performance Results

Cause or Trend	Impact on FDA's Commitments
Small meeting goal cohorts for some meetings and a smaller manufacturing prior approval supplement cohort	• A single missed goal has a large impact on performance when cohorts are smaller. For example, for certain meeting goals, such as BIA meeting scheduling, fewer than 10 meetings were requested. FDA would miss the 90 percent performance goal even if only one meeting goal was missed. • Fewer manufacturing prior approval supplements compared to FY 2021 meant the same small number of missed goals resulted in a drop below the 90 percent on-time performance goal.
Increasing resource-intensive workload across user fee programs strained the same set of key staff within relevant offices/divisions	• An increasing workload contributed to the overall challenge of scheduling and completing meetings on time. Logistical challenges also arose when scheduling necessary key individuals for meetings within goal dates. This trend particularly impacted meeting management performance of shorter goal meetings, such as BPD Type 1 and BPD Type 4 meetings. • An increasing proprietary name submission workload also impacted performance on proprietary name submission procedural goals during the BPD phase.

Appendix D: FY 2022 Corrective Action Report

On August 18, 2017, FDARA was signed into law. FDARA amended the FD&C Act to revise and extend the user fee programs for prescription drugs, generic drugs, medical devices, and biosimilar biological products, and for other purposes. Section 744I(c) of the FD&C Act, added by section 904(d) of FDARA, 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 II 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 below represents FDA's FY 2021 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 2021, then the Agency fully reported on it in last year's report.[5]

Table D-1. FY 2021 Review Goal Performance Results (Updated)

Goal Type	Circumstances and Trends Impacting the Ability to Meet the Goal Date	Corrective Action Plan
Procedural and Meeting	• 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 meeting goals.

Table D-2. FY 2022 Review Goal Performance Results

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Procedural and Meeting	• 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 strained the same set of key staff within relevant offices/divisions.	• FDA continues to assess ways to more effectively handle the procedural goals and meeting requests, as well as the increasing review workload.

FY 2022 Performance Enhancement Goal Performance Results

Table D-3. FY 2022 Performance Enhancement Goal Performance Results

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Management of Carryover Balance	• FDA needs to increase recurring spending to meet the BsUFA II carryover balance goal. Although FDA increased the number of BsUFA positions, filling those positions and backfilling attrition continues to be a challenge.	• As set forth in the BsUFA III Commitment Letter, FDA is committed to reducing the carryover balance to no greater than 21 weeks by the end of FY 2025 and will provide progress updates in the annual updates to the BsUFA five-year financial plan.

B. BsUFA Review Goals

The following section addresses section 744I(c)(2)(A) of the FD&C Act, added by section 904(d) of FDARA, which requires FDA to provide a justification for the determination of review

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

goals missed during FY 2021 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 II goals that were not met with required completion dates in FY 2022. This section also includes FDA's FY 2021 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 2021, then the Agency fully reported on it in the last fiscal year's report.

I. FY 2021 Updated Procedural and Meeting Performance Results

A. Summary of Performance:

FDA missed the procedural notification goal for proprietary name submitted during BPD phase.

B. Justification:

A single missed goal has a large impact on procedural goal performance. For proprietary name submitted during BPD phase, fewer than 10 submissions were received. FDA would miss the 90 percent performance goal even if only one procedural notification is not acted on within the goal time frame.

C. FY 2022 Corrective Actions:

FDA will continue to strive to meet all BsUFA procedural and meeting goals.

II. FY 2022 Review Goal Performance Results

A. Summary of Performance:

FDA is currently meeting or has the potential to meet all review performance goals for FY 2022.

III. FY 2022 Procedural and Meeting Performance Results

A. Summary of Performance:

FDA missed the following procedural notification and meeting management goals:

- Proprietary name submitted during BPD phase
- Meeting request response for BPD type 1, 2, and 4 meetings
- Meeting scheduling for BIA and BPD type 1 and 4 meetings
- Preliminary response for BPD type 2 meetings

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.

An increasing resource-intensive workload, combined with staffing challenges across user fee programs, strained the same set of key staff within relevant offices/divisions.

C. *FY 2023 Corrective Actions:*

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

C. BsUFA Performance Enhancement Goals

The following section addresses section 744I(c)(2)(B) of the FD&C Act, added by section 904(d) of FDARA, 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 such goal.

This section presents non-review performance goals cited in the BsUFA II Commitment Letter with required completion dates in FY 2022. In this report, "performance enhancement goals" are defined as any non-review performance goal described in the BsUFA II Commitment Letter with a specified goal date that falls within the applicable fiscal year.

I. Management of Carryover Balance

A. Summary of Performance:

FDA missed the goal to reduce the carryover balance to no greater than 33 weeks of the FY 2022 target revenue by the end of FY 2022.

B. Justification:

FDA needs to increase its recurring spending to meet the BsUFA II carryover balance goal. Although FDA increased the number of BsUFA positions, filling those positions and backfilling attrition continues to be a challenge.

C. FY 2023 Corrective Actions:

As set forth in the BsUFA III Commitment Letter, FDA (1) is committed to reducing the carryover balance to no greater than 21 weeks by the end of FY 2025 and (2) will provide progress updates in the annual updates to the BsUFA five-year financial plan.

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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