FY 2021

PERFORMANCE REPORT TO CONGRESS

for the

Biosimilar User Fee Act

Commissioner's Report

I am pleased to present to Congress the Food and Drug Administration's (FDA's or the Agency's) fiscal year (FY) 2021 Biosimilar User Fee Act (BsUFA) performance report. This report marks the ninth year of BsUFA and the fourth year of BsUFA II (which covers FY 2018 through FY 2022).

FY 2021 turned out to be a unique year due to the COVID-19 pandemic, creating unforeseen obstacles. Despite an increased workload and remote workforce, FDA maintained its level of performance in meeting BsUFA goals and initiatives. This report details FDA's preliminary performance results for FY 2021 and finalizes FDA's performance results for FY 2020. Although FDA has made substantial progress, there remains work to be done to ensure that the Agency meets all BsUFA performance goals. In FY 2020, FDA met or exceeded 17 of our 26 performance goals, and FDA expects to meet or exceed 16 of 27 performance goals that apply to the biosimilar submissions for the FY 2021 cohort.

FDA is dedicated to continually improving the efficiency, quality, and predictability of its biosimilar biological product review. In particular, to fulfill BsUFA's commitment to meet all of its performance goals going forward, FDA will continue to strengthen its efforts to improve performance while, as always, maintaining a focus on ensuring that all biosimilar biological product submissions are reviewed in an efficient and predictable time frame.

Also, FDA is committed to exploring new approaches and technologies that offer high-quality, cost-effective improvements for its review of biosimilar biological product submissions.

FDA looks forward to the continued success of and improvements to the biosimilar biological product review process, made possible by BsUFA, in the coming years.

Janet Woodcock, M.D.
Acting Commissioner of Food and Drugs

Acronyms

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
FY – Fiscal Year (October 1 to September 30)
OND – Office of New Drugs
PHS Act – Public Health Service Act
REMS – Risk Evaluation and Mitigation Strategy
WCF – Working Capital Fund

Executive Summary

The Biosimilar User Fee Act (BsUFA) provides funding to the Food and Drug Administration (FDA or Agency) 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 current set of 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 ninth year of the BsUFA program and the fourth year of BsUFA II. The report presents FDA's final performance results in meeting BsUFA goals and commitments for FY 2020 and FDA's preliminary performance results for FY 2021.

Program Performance

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. Key highlights for the BsUFA program include the following:

- Of the 28 BsUFA goal categories, 26 applied to FY 2020 biosimilar submissions. FDA met or exceeded 17 of these 26 goals.

- FDA has the potential to meet or exceed 16 of the 27 goals that apply to the FY 2021 cohort once these actions are completed.

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

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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.

Performance Results Presented in This Report

This report presents FDA's final performance results in meeting BsUFA goals and commitments for FY 2020 and FDA's preliminary performance results for FY 2021. These data represent FDA's performance on submissions received and actions taken as of September 30, 2021. Final FDA performance results for FY 2021 submissions will be presented in the FY 2022 BsUFA performance report and will include final actions for submissions still pending within the BsUFA goal date as of September 30, 2021. 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, 2021.
- 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 www.fda.gov/media/100573/download.

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BsUFA Workload

Workload: FY 2017 to FY 2021

The tables below present the workload numbers from FY 2017 to FY 2021.

Review Workload

BsUFA Workload	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
Biosimilar Applications and Supplements					
Original Biosimilar Product Applications	13	6	7	8*	8
Resubmitted Original Biosimilar Applications	2	6	4	1	5
Original Supplements with Clinical Data	0	3	12	2	7
Resubmitted Supplements with Clinical Data	0	0	0	1	1
Manufacturing Supplements †	7	NA	NA	NA	NA
Manufacturing Supplements Requiring Prior Approval	NA	6	22	43*	47
Manufacturing Supplements Not Requiring Prior Approval	NA	19	28	31*	46

* This number is modified from the preliminary data reported in FY 2020.

† Under BsUFA I, all manufacturing supplements were reported together under one performance goal.

Procedural and Meeting Workload

BsUFA Workload	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
Procedural Notifications					
Notification of Issues Identified During the Filing Review†	13	NA	NA	NA	NA
Notification of Issues Identified During the Filing Review for Supplements with Clinical Data§	NA	1	7	1	4
Notification of Planned Review Timeline†	13	NA	NA	NA	NA
Notification of Planned Review Timeline for Supplements with Clinical Data§	NA	1	6	1	4
Proprietary Name Submitted During BPD Phase	10	10	3	6	8
Proprietary Name Submitted During Application Review	16	15	15	10*	15
Procedural Responses					
Major Dispute Resolution	0	0	0	0	0
Responses to Clinical Holds	0	0	1	0	2
Special Protocol Assessments	3	3	2	2	1

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, 2021, 50 351(k) applications were accepted for filing by FDA.

As of September 30, 2021, 62 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 four biosimilar product applications that have not received an action and there are no supplements that have not received an action from the FY 2020 or earlier cohorts.

Original Biosimilar Product Applications Filed* and Approvals to Such Applications

Application Type	FY 2021 Filed*/Approved as of 9/30/2021
Original Biosimilar Product Applications	8 / 0
Resubmitted Original Biosimilar Product Applications	5 / 0

* 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, they have been withdrawn within 60 days of receipt, or they have been refused to file.

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.

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 2020 to FY 2021 in the number of FTEs hired as agreed upon in the BsUFA II Commitment Letter.

The hiring of FTEs decreased from FY 2020 to FY 2021 due to FDA fulfilling its hiring target of 15 FTEs under BsUFA II. Although the goal has now been met, FDA will increase staff as needed, if funding is available, to address the program workload.

Number of FTEs Hired As Agreed Upon in the BsUFA II Commitment Letter

Center	Number of FTEs Hired in FY 2020	Number of FTEs Hired in FY 2021	Change in Number of FTEs Hired
CDER	2	0	-2
CBER	0	0	0
ORA	0	0	0
OC	0	0	0

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 2020 to FY 2021 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 2080-hour workload to equate to one FTE, and this calculation is reflected in the table below. Data for FY 2021 and the previous fiscal year, FY 2020, 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 2020 are those FTEs as of September 30, 2020. The number of FTEs funded by budget authority for FY 2021 are those FTEs as of September 30, 2021.

Overall, FDA reported an increase in FTEs funded by budget authority in FY 2021 compared to FY 2020. The increase in FTEs funded by budget authority was attributable to increases in program workload compared to FY 2020.

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 2020	FY 2021	
CDER			
Office of Communications	0.2	0.9	0.7
Office of Compliance	0.5	0.6	0.1
Office of the Center Director	0.6	1.0	0.4
Office of Executive Programs	0.3	0.7	0.4
Office of Generic Drugs	0.0	0.1	0.1
Office of Medical Policy	1.8	0.2	-1.6
Office of Management	1.8	2.4	0.6
Office of New Drugs	8.9	10.2	1.3
Office of Pharmaceutical Quality	10.6	18.8	8.2
Office of Regulatory Policy	1.2	1.6	0.4
Office of Surveillance and Epidemiology	2.5	3.3	0.8
Office of Strategic Planning	1.4	1.4	0.0
Office of Information Management and Technology	0.2	0.2	0.0
Office of Translational Sciences	5.0	6.8	1.8
Other Offices	0.1	0.2	0.1
Working Capital Fund (WCF)	1.7	2.5	0.8
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	0.0	0.1	0.1
Office of Tissues and Advanced Therapies	0.0	0.1	0.1

Office of Vaccines Research and Review	0.1	0.0	-0.1
Office of Communication Outreach and Development	0.0	0.0	0.0
Office of the Center Director	0.2	0.2	0.0
Office of Management	0.0	0.1	0.1
WCF	0.0	0.0	0.0
OC			
Office of the Chief Counsel	1.3	0.3	-1.0
Office of Clinical Policy and Programs	0.5	0.0	-0.5
Office of Operations	1.4	1.0	-0.4
Office of Policy, Legislation, and International Affairs	0.4	0.1	-0.3
WCF	0.5	0.4	-0.1
ORA			
WCF	0.5	0.4	-0.1

* 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.

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 2020 and FY 2021, as well as the changes in these amounts from FY 2020 to FY 2021. 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 2021) and prior fiscal year (FY 2020).

The process for setting the annual target revenue is set forth in the statute. For FY 2021, the base revenue amount is the FY 2020 inflation adjusted fee revenue amount of $41,922,873. The

FY 2021 base revenue amount was adjusted for inflation. FDA did not make an adjustment to the fee amounts pursuant to the capacity planning adjustment or the operating reserve adjustment. This resulted in a target revenue amount of $42,493,000 (rounded to the nearest thousand) for FY 2021. In FY 2021, FDA had net collections of $43 million in BsUFA fees, spent $34 million in user fees for the BsUFA program, and carried forward a cumulative balance of $46 million for future fiscal years. Detailed financial information for the BsUFA user fee program can be found in the FY 2021 BsUFA financial report.

In FY 2021, BsUFA obligations remained constant compared to FY 2020.

Changes in the Fee Revenue Amounts and Review Process Costs

Fiscal Year	FY 2020	FY 2021	Change from FY 2020 to FY 2021
Net Fiscal Year Collections	$37,971,967	$42,705,959	12%
Review Process Cost	$56,334,753	$55,928,075	-1%

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, 2021.

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

Time Reporting Requirement for FY 2021

Center	FTEs for Which Time Reporting Is Required	FTEs for Which Time Reporting Is Not Required
CDER	5,315	45
CBER	1,194	18
ORA	3,111	1,804
OC	41	2,609

Appendices

Appendix A: Performance Calculations

The following tables detail the final performance for FY 2020 and preliminary performance for the FY 2021 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 2020 and current performance for FY 2021). 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 2020 performance data presented here have been updated from the preliminary performance information reported in the FY 2020 BsUFA performance report.

Review Goal Performance

Biosimilar Applications and Supplements

Original Biosimilar Product Applications	FY 2020	FY 2021
Total Filed Submissions (Workload)	**8**	**8**
Pending Within Goal	0	8
On Time	4	0
Overdue	4	0
Performance: % On Time	**50%**	**--**
Highest Possible Performance	**50%**	**100%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Not Met**	**Currently Meeting, Pending**

Resubmitted Original Biosimilar Applications	FY 2020	FY 2021
Total Submissions (Workload)	1	**5**
Pending Within Goal	0	2
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**	**Currently Meeting, Pending**

Original Supplements with Clinical Data	FY 2020	FY 2021
Total Filed Submissions (Workload)	**2**	**7**
Pending Within Goal	0	7
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, Pending**

Resubmitted Supplements with Clinical Data	FY 2020	FY 2021
Total Submissions (Workload)	**1**	**1**
Pending Within Goal	0	0
On Time	1	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**

Manufacturing Supplements Requiring Prior Approval	FY 2020	FY 2021
Total Filed Submissions (Workload)	**43**	**47**
Pending Within Goal	0	13
On Time	41	32
Overdue	2	2
Performance: % On Time	**95%**	**94%**
Highest Possible Performance	**95%**	**96%**
BsUFA Goal: On Time Target %	**80%**	**85%**
Goal Met Status	**Goal Met**	**Currently Meeting, Pending**

Manufacturing Supplements Not Requiring Prior Approval	FY 2020	FY 2021
Total Filed Submissions (Workload)	**31**	**46**
Pending Within Goal	0	29
On Time	30	17
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**

Procedural and Meeting Goal Performance

Procedural Notifications

Notification of Issues Identified During the Filing Review for Supplements with Clinical Data	FY 2020	FY 2021
Total Filed Submissions (Workload)	**1**	**4**
Pending Within Goal	0	1
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**	**Currently Meeting, Pending**

Notification of Planned Review Timeline for Supplements with Clinical Data	FY 2020	FY 2021
Total Filed Submissions (Workload)	**1**	**4**
Pending*	0	1
In 74-Day Letter	1	3
Not in 74-Day Letter	0	0
Performance:	**100%**	**100%**
Highest Possible Performance	**100%**	**100%**
BsUFA Goal:	**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 2020	FY 2021
Total Submissions (Workload)	**6**	**8**
Pending Within Goal	0	4
On Time	6	4
Overdue	0	0
Current 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**

Proprietary Name Submitted During Application Review	FY 2020	FY 2021
Total Submissions (Workload)	**10**	**15**
Pending Within Goal	0	3
On Time	10	11
Overdue	0	1
Performance: % On Time	**100%**	**92%**
Highest Possible Performance	**100%**	**93%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Met**	**Currently Meeting, Pending**

Procedural Responses

Major Dispute Resolution	FY 2020	FY 2021
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**

Meeting Minutes: All Meeting Types	FY 2020	FY 2021
Total Submissions (Workload)	**52**	**68**
Pending Within Goal	0	21
On Time	46	38
Overdue	6	9
Performance: % On Time	**88%**	**81%**
Highest Possible Performance	**88%**	**87%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status	**Goal Not Met**	**Will Not Meet Goal**

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,[1] 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.

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] www.fda.gov/regulatory-information/search-fda-guidance-documents/good-review-management-principles-and-practices-new-drug-applications-and-biologics-license. This draft guidance, when finalized, will represent the current thinking of FDA on this topic.

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 (PREA), 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.[2]

[2] Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, available at 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 2021, 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 2021, 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.

Application Type	Performance Goal: Act on 90 Percent Within	Filed in FY 2021*	Approved in FY 2021	On Time†	Overdue†	Percent on Time
Original Biosimilar Applications	10 months of the 60-day filing date	8	3	3	0	100%
Resubmitted Original Biosimilar Applications	6 months of the receipt date	5	0	--	--	--
Original Supplements with Clinical Data	10 months of the receipt date	7	1	1	0	100%
Resubmitted Supplements with Clinical Data	6 months of the receipt date	1	0	--	--	--
Total		**21**	**4**	**4**	**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

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 www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/ucm624595.htm.

For 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.

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
Publication of Interim Assessment of the BsUFA Program	12/31/2020	Y	12/4/2020	BsUFA II: Assessment of the Program for Enhanced Review Transparency and Communication in the Biosimilar User Fee Act (see www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-ii-assessment-program-enhanced-review-transparency-and-communication-biosimilar-user-fee-act).
Public Meeting on the Interim Assessment of the BsUFA Program	3/31/2021	Y	1/27/2021	Public Meeting: Interim Assessment of the Program for Enhanced Review Transparency and Communication in the Biosimilar User Fee Act (see www.fda.gov/drugs/news-events-human-drugs/public-meeting-interim-assessment-program-enhanced-review-transparency-and-communication-biosimilar).
2021 Annual Update to the 5-Year Plan	3/31/2021	Y	3/30/2021	Five Year Financial Plan Fiscal Years 2018-2019-2020-2021-2022, 2021 Update for the Biosimilar User Fee Act Program (see www.fda.gov/media/147059/download).
FY 2021 Financial Public Meetings	6/30/2021	Y	6/28/2021	Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments (see www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and).

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.

The table below represents FDA's FY 2020 updated performance results.

Cause or Trend	Impact on FDA's Commitments
Original biosimilar product application cohort is small	A single missed goal has a large impact on review goal performance. For original biosimilar applications, because fewer than 10 applications were received, FDA would miss the 90 percent performance goal even if only one application is not acted on within the goal time frame.
COVID-19 public health emergency	FDA experienced considerable increases in COVID-19-related work, requiring shifting of staff resources to support these activities, which impacted the goals that were missed.

The table below represents FDA's FY 2021 preliminary performance results.

Cause or Trend	Impact on FDA's Commitments
Meeting management cohort is small	A single missed goal has a large impact on meeting management performance. For example, for certain meeting goals, such as a response to BIA, BPD Type 3 and BPD Type 4 meeting requests, and BPD Type 3 and BPD Type 4 meeting scheduling, fewer than 10 meetings were requested. FDA would miss the 90 percent performance goal even if only one meeting goal was missed in these categories.
Increasing the resource-intensive meeting workload across user fee programs strained the same set of key staff within relevant offices/divisions	Increasing workload contributed to the overall challenge of scheduling meetings and of completing meeting and written responses on time. Logistical challenges also arose when scheduling necessary key individuals for meetings within goal dates. This trend particularly impacted meeting management performance for higher volume meetings, such as BPD Type 2 meetings.
COVID-19 public health emergency	FDA continued to be impacted by COVID-19-related work and travel limitations in FY 2021, which also impacted BsUFA performance goals.

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Appendix D: FY 2021 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.

Executive Summary

FY 2020 Updated Review Goal Performance Results

The following table represents FDA's FY 2020 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 2020, then the Agency fully reported on it in last year's report.[1]

FY 2020 Review Goal Performance Results (Updated)

Goal Type	Circumstances and Trends Impacting the Ability to Meet the Goal Date	Corrective Action Plan
Review Goals	• 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. • The COVID-19 public health emergency impacted FDA's ability to meet the review goal for original biosimilar product applications.	• FDA continues to strive to meet all BsUFA review goals, with all FY 2021 original biosimilar product applications currently pending within goal.

FY 2021 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. • The COVID-19 public health emergency and an increasing resource-intensive meeting workload across user fee programs strained the same set of key staff within relevant offices/divisions.	• FDA will continue to strive to meet all BsUFA procedural and meeting goals. • Better alignment of resources from the Office of New Drugs (OND) reorganization, which completed in FY 2020, and the application of more resources when the urgency of devoting OND staff to FDA's pandemic response decreases are expected to facilitate meeting BsUFA goals.

FY 2021 Performance Enhancement Goal Performance Results

All FY 2021 Performance Enhancement Goals were met.

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

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 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 2021. This section also includes FDA's FY 2020 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 2020, then the Agency fully reported on it in the last fiscal year's report.

I. FY 2020 Updated Review Goal Performance Results

A. Summary of Performance Results

FDA missed the review performance goal for original biosimilar product applications.

B. Justification

- The COVID-19 public health emergency impacted FDA's ability to meet the review goal for original biosimilar product applications.
- A single missed goal has a large impact on review goal performance. For original biosimilar applications, fewer than 10 applications were received. FDA would miss the 90 percent performance goal even if only one application is not acted on within the goal time frame.

C. FY 2021 Corrective Actions

All original biosimilar product applications in the FY 2021 cohort are currently pending within the goal date.

II. FY 2021 Procedural and Meeting Performance Results

A. Summary of Performance Results

- FDA is currently meeting all procedural response goals.
- FDA missed the following meeting management goals:
    - Meeting request response for BIA and BPD Type 2, 3, and 4 meetings

- Meeting scheduling for BPD Types 1, 2, 3 and 4 meetings
- Preliminary Response for BPD Type 2 and 3 meetings
- Meeting minutes, all meeting types

B. Justification

Contributing factors in missing meeting management goals include the following:

- The BsUFA meeting management cohort is small.
    - A single missed goal has a large impact on performance. For example, for certain meeting goals (e.g., the scheduling of BPD Type 1, 3, or 4 meetings), because fewer than 10 meetings were requested, FDA will miss the 90 percent performance goal even if only one meeting is not scheduled within the goal time frame.
- There was an increase in the preliminary response performance goal from 80% to 85% for BPD Type 2 meetings.
- The COVID-19 public health emergency and an increasing resource-intensive meeting workload across user fee programs strained the same set of key staff within relevant offices/divisions and contributed to the overall challenge of scheduling meetings, completing meeting responses, preparing meeting minutes, and sending written responses on time. Logistically, there are times when it can be challenging to schedule necessary key individuals for meetings within the goal dates.

C. FY 2022 Corrective Actions

- FDA will continue to strive to meet all procedural response goal dates.
- Better alignment of resources from the OND reorganization and the application of more resources when the urgency of devoting OND staff to FDA's pandemic response decreases are expected to facilitate FDA's ability to meet the BsUFA meeting goals.

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 2021. 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. Performance enhancement goals with specified completion dates in FY 2022 will be covered in subsequent corrective action reports.

FDA met all FY 2021 performance enhancement goals.

This report was prepared by FDA's Office of Planning in collaboration with FDA's Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research). For information on obtaining additional copies, contact:

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