U.S. FOOD & DRUG ADMINISTRATION

FY 2019

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 or the Agency) Fiscal Year (FY) 2019 Biosimilar User Fee Act (BsUFA) performance report. This report marks the seventh year of BsUFA and the second year of BsUFA II (FY 2018 through FY 2022).

FDA is dedicated to improving the efficiency, quality, and predictability of the biosimilar biological product review. This report details FDA's preliminary performance for FY 2019 and finalizes performance results for FY 2018. Although we have made substantial progress, there remains work to be done to ensure that we meet all BsUFA performance goals. In FY 2018, FDA met or exceeded 22 of our 25 performance goals, and we expect to meet or exceed 15 of 25 performance goals that apply to the biosimilar submissions for the FY 2019 cohort.

In order to achieve our commitment to meeting all BsUFA performance goals going forward, we will continue to strengthen 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.

We are also committed to exploring new approaches and technologies that offer high-quality, cost-effective improvements in FDA's review of biosimilar biological product submissions.

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

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs

Acronyms

BPCIA – Biologics Price Competition and Innovation Act of 2009

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

FDASIA – Food and Drug Administration Safety and Innovation Act

FY – Fiscal Year (October 1 to September 30)

PHS Act – Public Health Service Act

REMS – Risk Evaluation and Mitigation Strategy

Executive Summary

The Biosimilar User Fee Act (BsUFA) provides funding for the review of biosimilar biological products. The Food and Drug Administration (FDA or the Agency) developed proposed enhancements for BsUFA II in consultation with regulated industry representatives, patient and consumer advocates, health care professionals, and other public stakeholders. These discussions led to the current set of performance goals for the Fiscal Year (FY) 2018-2022 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 seventh year of the BsUFA program and the second year of BsUFA II. The report presents FDA's final performance in meeting BsUFA goals and commitments for FY 2018 and preliminary performance for FY 2019.

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, 25 applied to FY 2018 biosimilar submissions. FDA met or exceeded 22 of these 25 goals.

- FDA has the potential to meet or exceed 15 of the 25 goals that apply to the FY 2019 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 (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 the 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 biosimilar biological products for the American public.

Performance Presented in This Report

This report presents FDA's final performance in meeting BsUFA goals and commitments for FY 2018 and preliminary performance for FY 2019. These data represent FDA's performance on submissions received and actions taken as of September 30, 2019. Final FDA performance for FY 2019 submissions will be presented in the FY 2020 BsUFA Performance Report and will include final actions for submissions still pending within the BsUFA goal date as of September 30, 2019. 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 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 does 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, 2019.
- 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 BsUFA II Commitment Letter 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 has been 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.
- **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 to FDA to approve a change in the manufacturing of an approved biosimilar.

Additional definitions are included in Appendix B.

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 BsUFA performance metrics and definitions for Biosimilar Biological Product Development (BPD) meeting types can be found in Appendix B.

FDA Performance Review Goals

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%

FDA Performance Procedural and Meeting Goals

BsUFA Submission Type	Goal	FY 18	FY 19	FY 20	FY 21	FY 22
Procedural Notifications						
Notification of Issues Identified During Filing Review for Supplements with Clinical Data	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%
Review of Proprietary Names During BPD Phase	Review within 180 days	90%	90%	90%	90%	90%
Review of Proprietary Names During Application Review	Review 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%

FDA Performance Procedural and Meeting Goals (continued)

BsUFA Submission Type	Goal	FY 18	FY 19	FY 20	FY 21	FY 22
Meeting Management						
Meeting Requests: Biosimilar Initial Advisory	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: Biosimilar Initial Advisory	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: Biosimilar Initial Advisory	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%

FY 2018 Final BsUFA Performance Summary

FY 2018 final BsUFA performance is presented in the tables below. The details of the percentages can be found in Appendix A.

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

Of the 28 BsUFA goal categories, 25 applied to FY 2018 biosimilar submissions. FDA met or exceeded 22 of these 25 goals. No submissions were received for 3 of the 28 BsUFA goal categories that are indicated with an "NA" in the tables below.

FY 2018 Final Review Goal Performance

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	6 of 6	90%	100%	Yes
Resubmitted Original Biosimilar Applications	6 months	6 of 6	90%	100%	Yes
Original Supplements with Clinical Data	10 months	3 of 3	90%	100%	Yes
Resubmitted Supplements with Clinical Data	6 months	0 of 0	90%	NA*	NA*
Manufacturing Supplements Requiring Prior Approval	4 months	6 of 6	70%	100%	Yes
Manufacturing Supplements Not Requiring Prior Approval	6 months	19 of 19	90%	100%	Yes

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

FY 2018 Final Procedural and Meeting Goal Performance

BsUFA Submission Type	Goal	On Time	Performance Goal	Percent on Time	Goal Met
Procedural Notifications					
Notification of Issues Identified During Filing Review for Supplements with Clinical Data	Notify within 74 days	1 of 1	90%	100%	Yes
Notification of Planned Review Timeline for Supplements with Clinical Data	Notify within 74 days	1 of 1	90%	100%	Yes
Review of Proprietary Names During BPD Phase	Review within 180 days	10 of 10	90%	100%	Yes
Review of Proprietary Names During Application Review	Review within 90 days	15 of 15	90%	100%	Yes
Procedural Responses					
Major Dispute Resolution	Respond within 30 days	0 of 0	90%	NA*	NA*
Responses to Clinical Holds	Respond within 30 days	0 of 0	90%	NA*	NA*
Special Protocol Assessments	Respond within 45 days	3 of 3	90%	100%	Yes

FY 2018 Final Procedural and Meeting Goal Performance (continued)

BsUFA Submission Type	Goal	On Time	Performance Goal	Percent on Time	Goal Met
Meeting Management					
Meeting Requests: Biosimilar Initial Advisory	Respond within 21 days	12 of 12	90%	100%	Yes
Meeting Requests: BPD Type 1	Respond within 14 days	6 of 6	90%	100%	Yes
Meeting Requests: BPD Type 2	Respond within 21 days	44 of 47	90%	94%	Yes
Meeting Requests: BPD Type 3	Respond within 21 days	1 of 1	90%	100%	Yes
Meeting Requests: BPD Type 4	Respond within 21 days	6 of 6	90%	100%	Yes
Scheduling Meetings: Biosimilar Initial Advisory	Schedule within 75 days	3 of 5	90%	60%	No
Scheduling Meetings: BPD Type 1	Schedule within 30 days	4 of 5	90%	80%	No
Scheduling Meetings: BPD Type 2	Schedule within 90 days	28 of 31	80%	90%	Yes
Scheduling Meetings: BPD Type 3	Schedule within 120 days	1 of 1	90%	100%	Yes
Scheduling Meetings: BPD Type 4	Schedule within 60 days	5 of 6	90%	83%	No
Written Response: Biosimilar Initial Advisory	Respond within 75 days	1 of 1	90%	100%	Yes
Written Response: BPD Type 2	Respond within 90 days	9 of 10	80%	90%	Yes
Preliminary Responses: BPD Type 2	Issue no later than 5 days prior to meeting date	26 of 30	70%	87%	Yes
Preliminary Responses: BPD Type 3	Issue no later than 5 days prior to meeting date	1 of 1	90%	100%	Yes
Meeting Minutes: All Meeting Types	Issue within 30 days after meeting date	39 of 43	90%	91%	Yes

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

FY 2019 Preliminary BsUFA Performance Summary

FY 2019 BsUFA performance is presented in the tables below.

- The *Actions Completed* column shows how much of the cohort has been acted on so far by presenting the number of submissions that had actions taken in FY 2019 or were overdue as of September 30, 2019, 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, 2019. Actions that were pending and not yet past the goal date as of September 30, 2019, 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 (by the BsUFA goal date).

FDA has the potential to meet or exceed 15 of the 25 goals that apply to the FY 2019 cohort once these actions are completed.

FY 2019 Preliminary Review Goal Performance

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 7 Complete	10 months from 60-day filing date	90%	--	100%
Resubmitted Original Biosimilar Applications	3 of 4 complete	6 months	90%	75%	75%
Original Supplements with Clinical Data	5 of 12 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	11 of 22 complete	4 months	75%	92%	95%
Manufacturing Supplements Not Requiring Prior Approval	10 of 30 complete	6 months	90%	100%	100%

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

FY 2019 Preliminary Procedural and Meeting Goal Performance

BsUFA Submission Type	Actions Completed	Goal	Performance Goal	Percent on Time	Highest Possible Performance
Procedural Notifications					
Notification of Issues Identified During Filing Review for Supplements with Clinical Data	6 of 7 complete	Notify within 74 days	90%	100%	100%
Notification of Planned Review Timeline for Supplements with Clinical Data	6 of 7 complete	Notify within 74 days	90%	100%	100%
Review of Proprietary Names During BPD Phase	2 of 4 complete	Review within 180 days	90%	100%	100%
Review of Proprietary Names During Application Review	11 of 15 complete	Review 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	1 of 1 complete	Respond within 30 days	90%	100%	100%
Special Protocol Assessments	2 of 2 complete	Respond within 45 days	90%	100%	100%
Meeting Management					
Meeting Requests: Biosimilar Initial Advisory	9 of 10 complete	Respond within 21 days	90%	70%	70%
Meeting Requests: BPD Type 1	9 of 9 complete	Respond within 14 days	90%	89%	89%
Meeting Requests: BPD Type 2	73 of 77 complete	Respond within 21 days	90%	99%	99%
Meeting Requests: BPD Type 3	8 of 9 complete	Respond within 21 days	90%	88%	89%
Meeting Requests: BPD Type 4	7 of 8 complete	Respond within 21 days	90%	100%	100%
Scheduling Meetings: Biosimilar Initial Advisory	6 of 6 complete	Schedule within 75 days	90%	50%	50%
Scheduling Meetings: BPD Type 1	8 of 8 complete	Schedule within 30 days	90%	63%	63%
Scheduling Meetings: BPD Type 2	52 of 58 complete	Schedule within 90 days	80%	77%	79%
Scheduling Meetings: BPD Type 3	8 of 9 complete	Schedule within 120 days	90%	100%	100%
Scheduling Meetings: BPD Type 4	6 of 7 complete	Schedule within 60 days	90%	33%	43%
Written Response: Biosimilar Initial Advisory	0 of 0 complete	Respond within 75 days	90%	NA*	NA*
Written Response: BPD Type 2	10 of 14 complete	Respond within 90 days	80%	82%	86%

Preliminary Responses: BPD Type 2	40 of 52 complete	Issue no later than 5 days prior to meeting date	75%	85%	88%
Preliminary Responses: BPD Type 3	5 of 8 complete	Issue no later than 5 days prior to meeting date	90%	60%	75%
Meeting Minutes: All Meeting Types	46 of 71 complete	Issue within 30 days after meeting date	90%	73%	82%

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

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BsUFA Workload

Workload: FY 2015 to FY 2019

The tables below present the workload numbers from FY 2015 to FY 2019.

Review Workload

BsUFA Workload	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Biosimilar Applications and Supplements					
Original Biosimilar Product Applications	5	3	13	6	7
Resubmitted Original Biosimilar Applications	0	1	2	6	4
Original Supplements with Clinical Data	0	0	0	3*	12
Resubmitted Supplements with Clinical Data	0	0	0	0	0
Manufacturing Supplements †	0	7	7	NA	NA
Manufacturing Supplements Requiring Prior Approval	NA	NA	NA	6*	22
Manufacturing Supplements Not Requiring Prior Approval	NA	NA	NA	19*	30

* Number modified from preliminary data reported in FY 2018.

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

Procedural and Meeting Workload

BsUFA Workload	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Procedural Notifications					
Notification of Issues Identified During Filing Review†	5	3	13	NA	NA
Notification of Issues Identified During Filing Review for Supplements with Clinical Data§	NA	NA	NA	1	7
Notification of Planned Review Timeline†	5	3	13	NA	NA
Notification of Planned Review Timeline for Supplements with Clinical Data§	NA	NA	NA	1	7
Review of Proprietary Names During BPD Phase	5	14	10	10	4
Review of Proprietary Names During Application Review	7	10	16	15*	15
Procedural Responses					
Major Dispute Resolution	0	0	0	0	0
Responses to Clinical Holds	2	3	0	0	1
Special Protocol Assessments	1	2	3	3	2

* Number modified from preliminary data reported in FY 2018.

† Under BsUFA I, notifications for original applications and supplements with clinical data were reported together under one performance goal.

§ Under BsUFA II, notifications for supplements with clinical data are reported as a separate performance goal.

Procedural and Meeting Workload (continued)

BsUFA Workload	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Meeting Management					
Meeting Requests: Biosimilar Initial Advisory	3	10	12	12	10
Meeting Requests: BPD Type 1	3	9	4	6	9
Meeting Requests: BPD Type 2	48	45	59	47	77
Meeting Requests: BPD Type 3	1	5	3	1	9
Meeting Requests: BPD Type 4	3	11	10	6	8
Scheduling Meetings: Biosimilar Initial Advisory	2	8	9	5	6
Scheduling Meetings: BPD Type 1	3	8	4	5	8
Scheduling Meetings: BPD Type 2	41	41	49	31*	58
Scheduling Meetings: BPD Type 3	1	5	3	1	9
Scheduling Meetings: BPD Type 4	3	10	10	6	7
Written Response: Biosimilar Initial Advisory	NA	NA	NA	1	0
Written Response: BPD Type 2	NA	NA	NA	10*	14
Preliminary Responses: BPD Type 2	NA	NA	NA	30*	52
Preliminary Responses: BPD Type 3	NA	NA	NA	1	8
Meeting Minutes: All Meeting Types	47	64	58	43	71

* Number modified from preliminary data reported in FY 2018.

Additional Reporting Requirements

Section 408 of the Food and Drug Administration Safety and Innovation Act (FDASIA) requires that, beginning in FY 2014, FDA report the following:

- The number of applications for approval filed under section 351(k) of the Public Health Service Act (PHS Act);
- The percentage of applications described in subparagraph (A) of section 408 (i.e., above bullet) that were approved by the Secretary; 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 Federal Food, Drug, and Cosmetic Act (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, 2019, 36 351(k) applications were accepted for filing by FDA.

As of September 30, 2019, 64 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 of FDARA 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 approvals letters issued by the Agency for such applications.

There are no biosimilar product applications and supplements from the FY 2018 or earlier cohorts that have not received an action.

Original Biosimilar Product Applications Filed* and Approvals to Such Applications

Application Type	FY 19 Filed*/ Approved as of 9/30/2019
Original Biosimilar Product Applications	7 / 0
Resubmitted Original Biosimilar Product Applications	4 / 2

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

Appendices

Appendix A: Performance Calculations

The following tables detail the final performance for FY 2018 and preliminary performance for the FY 2019 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 2018 and current performance for FY 2019). 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 2018 performance data presented here have been updated from the preliminary performance information reported in the FY 2018 BsUFA performance report.

Review Goal Performance

Biosimilar Applications and Supplements

Original Biosimilar Product Applications	FY 2018	FY 2019
Total Filed Submissions (Workload)	**6**	**7**
Pending Within Goal	0	7
On Time	6	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 Original Biosimilar Applications	FY 2018	FY 2019
Total Submissions (Workload)	**6**	**4**
Pending Within Goal	0	0
On Time	6	3
Overdue	0	1
Performance: % On Time	**100%**	**75%**
Highest Possible Performance:	**100%**	**75%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status:	**Goal Met**	**Will Not Meet Goal**

Original Supplements with Clinical Data	FY 2018	FY 2019
Total Filed Submissions (Workload)	**3**	**12**
Pending Within Goal	0	7
On Time	3	5
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**

Resubmitted Supplements with Clinical Data	FY 2018	FY 2019
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**

Manufacturing Supplements Requiring Prior Approval	FY 2018	FY 2019
Total Filed Submissions (Workload)	**6**	**22**
Pending Within Goal	0	10
On Time	6	11
Overdue	0	1
Performance: % On Time	**100%**	**92%**
Highest Possible Performance:	**100%**	**95%**
BsUFA Goal: On Time Target %	**70%**	**75%**
Goal Met Status:	**Goal Met**	**Currently Meeting, Pending**

Manufacturing Supplements Not Requiring Prior Approval	FY 2018	FY 2019
Total Filed Submissions (Workload)	**19**	**30**
Pending Within Goal	0	20
On Time	19	10
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**

Procedural and Meeting Goal Performance

Procedural Notifications

Notification of Issues Identified During Filing Review for Supplements with Clinical Data	FY 2018	FY 2019
Total Filed Submissions (Workload)	**1**	**7**
Pending Within Goal	0	1
On Time	1	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 2018	FY 2019
Total Filed Submissions (Workload)	**1**	**7**
Pending*	0	1
In 74-Day Letter	1	6
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 receipt of original submission.

Review of Proprietary Names During BPD Phase	FY 2018	FY 2019
Total Submissions (Workload)	**10**	**4**
Pending Within Goal	0	2
On Time	10	2
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**

Review of Proprietary Names During Application Review	FY 2018	FY 2019
Total Submissions (Workload)	**15**	**15**
Pending Within Goal	0	4
On Time	15	11
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**

Procedural Responses

Major Dispute Resolution	FY 2018	FY 2019
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 2018	FY 2019
Total Submissions (Workload)	**0**	**1**
Pending Within Goal	0	0
On Time	0	1
Overdue	0	0
Performance: % On Time	**NA**	**100%**
Highest Possible Performance:	**NA**	**100%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status:	**NA**	**Will Meet Goal**

Special Protocol Assessments*	FY 2018	FY 2019
Total Submissions (Workload)	**3**	**2**
Pending Within Goal	0	0
On Time	3	2
Overdue	0	0
Performance: % On Time	**100%**	**100%**
Highest Possible Performance:	**100%**	**100%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status:	**Goal Met**	**Will Meet Goal**

* There were no resubmitted Special Protocol Assessments received in FY 2018.

Meeting Management[1]

Responses to Meeting Requests: Biosimilar Initial Advisory	FY 2018	FY 2019
Total Submissions (Workload)	**12**	**10**
Pending Within Goal	0	0
On Time	12	7
Overdue	0	3
Performance: % On Time	**100%**	**70%**
Highest Possible Performance:	**100%**	**70%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status:	**Goal Met**	**Will Not Meet Goal**

[1] 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 2018	FY 2019
Total Submissions (Workload)	**6**	**9**
Pending Within Goal	0	0
On Time	6	8
Overdue	0	1
Performance: % On Time	**100%**	**89%**
Highest Possible Performance:	**100%**	**89%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status:	**Goal Met**	**Will Not Meet Goal**

Responses to Meeting Requests: BPD Type 2	FY 2018	FY 2019
Total Submissions (Workload)	**47**	**77**
Pending Within Goal	0	4
On Time	44	72
Overdue	3	1
Performance: % On Time	**94%**	**99%**
Highest Possible Performance:	**94%**	**99%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status:	**Goal Met**	**Currently Meeting, Pending**

Responses to Meeting Requests: BPD Type 3	FY 2018	FY 2019
Total Submissions (Workload)	**1**	**9**
Pending Within Goal	0	1
On Time	1	7
Overdue	0	1
Performance: % On Time	**100%**	**88%**
Highest Possible Performance:	**100%**	**89%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status:	**Goal Met**	**Will Not Meet Goal**

Responses to Meeting Requests: BPD Type 4	FY 2018	FY 2019
Total Submissions (Workload)	**6**	**8**
Pending Within Goal	0	1
On Time	6	7
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**

Scheduling Meetings: Biosimilar Initial Advisory	FY 2018	FY 2019
Total Submissions (Workload)	**5**	**6**
Pending Within Goal	0	0
On Time	3	3
Overdue	2	3
Performance: % On Time	**60%**	**50%**
Highest Possible Performance:	**60%**	**50%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status:	**Goal Not Met**	**Will Not Meet Goal**

Scheduling Meetings: BPD Type 1	FY 2018	FY 2019
Total Submissions (Workload)	**5**	**8**
Pending Within Goal	0	0
On Time	4	5
Overdue	1	3
Performance: % On Time	**80%**	**63%**
Highest Possible Performance:	**80%**	**63%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status:	**Goal Not Met**	**Will Not Meet Goal**

Scheduling Meetings: BPD Type 2	FY 2018	FY 2019
Total Submissions (Workload)	**31**	**58**
Pending Within Goal	0	5
On Time	28	41
Overdue	3	12
Performance: % On Time	**90%**	**77%**
Highest Possible Performance:	**90%**	**79%**
BsUFA Goal: On Time Target %	**80%**	**80%**
Goal Met Status:	**Goal Met**	**Will Not Meet Goal**

Scheduling Meetings: BPD Type 3	FY 2018	FY 2019
Total Submissions (Workload)	**1**	**9**
Pending Within Goal	0	1
On Time	1	8
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**

Scheduling Meetings: BPD Type 4	FY 2018	FY 2019
Total Submissions (Workload)	**6**	**7**
Pending Within Goal	0	1
On Time	5	2
Overdue	1	4
Performance: % On Time	**83%**	**33%**
Highest Possible Performance:	**83%**	**43%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status:	**Goal Not Met**	**Will Not Meet Goal**

Written Response: Biosimilar Initial Advisory	FY 2018	FY 2019
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**

Written Response: BPD Type 2	FY 2018	FY 2019
Total Submissions (Workload)	**10**	**14**
Pending Within Goal	0	3
On Time	9	9
Overdue	1	2
Performance: % On Time	**90%**	**82%**
Highest Possible Performance:	**90%**	**86%**
BsUFA Goal: On Time Target %	**80%**	**80%**
Goal Met Status:	**Goal Met**	**Currently Meeting, Pending**

Preliminary Responses: BPD Type 2	FY 2018	FY 2019
Total Submissions (Workload)	**30**	**52**
Pending Within Goal	0	12
On Time	26	34
Overdue	4	6
Performance: % On Time	**87%**	**85%**
Highest Possible Performance:	**87%**	**88%**
BsUFA Goal: On Time Target %	**70%**	**75%**
Goal Met Status:	**Goal Met**	**Currently Meeting, Pending**

Preliminary Responses: BPD Type 3	FY 2018	FY 2019
Total Submissions (Workload)	**1**	**8**
Pending Within Goal	0	3
On Time	1	3
Overdue	0	2
Performance: % On Time	**100%**	**60%**
Highest Possible Performance:	**100%**	**75%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status:	**Goal Met**	**Will Not Meet Goal**

Meeting Minutes: All Meeting Types	FY 2018	FY 2019
Total Submissions (Workload)	**43**	**71**
Pending Within Goal	0	23
On Time	39	35
Overdue	4	13
Performance: % On Time	**91%**	**73%**
Highest Possible Performance:	**91%**	**82%**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status:	**Goal Met**	**Will Not Meet Goal**

Appendix B: Definitions of Key Terms

A. 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.

B. Goal Date Extensions

1. 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.

2. 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/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.

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.

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

D. A Biosimilar Initial Advisory (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.

E. 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.

F. 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.

G. 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.

H. 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 to 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 titled "Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022."

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 904(d) of FDARA, pertaining to BsUFA, which requires FDA to include 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 1 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 2019, 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 2019, 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 2019*	Approved in FY 2019	On Time†	Overdue†	Percent on Time
Original Biosimilar Applications	10 months of the 60-day filing date	7	5	5	0	100%
Resubmitted Original Biosimilar Applications	6 months of the receipt date	4	6	6	0	100%
Original Supplements with Clinical Data	10 months of the receipt date	12	6	6	0	100%
Resubmitted Supplements with Clinical Data	6 months of the receipt date	0	0	0	0	NA
Total		**23**	**17**	**17**	**0**	**--‡**

* For the purposes of 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.

† On time and overdue metrics 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 904(d) of FDARA, pertaining to BsUFA, which requires FDA to include 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 the purposes of 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
BSUFA FY18 Hiring Web Posting Quarter 4	10/14/2018	Y	10/9/2018	Food and Drug Administration Reauthorization Act of 2017 (FDARA) Hiring Data www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data
Publish final guidance on Best Practices for Communication Between IND Sponsors and FDA During Drug Development	12/31/2018	Y	12/29/2017	Best Practices for Communication Between IND Sponsors and FDA During Drug Development www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-communication-between-ind-sponsors-and-fda-during-drug-development
Published draft guidance describing processes and further considerations related to post-approval manufacturing changes for biosimilar biological products	3/31/2019	Y	12/11/2018	The guidance for this topic is included in the published draft guidance on New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2) as Q.I.20 www.fda.gov/regulatory-information/search-fda-guidance-documents/new-and-revised-draft-qas-biosimilar-development-and-bpci-act-revision-2
Publish Five-Year Financial Plan Fiscal Years 2018-2019-2020-2021-2022, 2019 Update for BsUFA (public report)	3/31/2019	N	5/31/2019	FDA published the FY 2019 BsUFA Five-Year Financial Plan update in May 2019 www.fda.gov/media/127001/download
Publish final guidance on Considerations in Demonstrating Interchangeability with a Reference Product	5/19/2019	Y	5/10/2019	Considerations in Demonstrating Interchangeability with a Reference Product www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-demonstrating-interchangeability-reference-product-guidance-industry
Publish draft guidance on Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations	5/21/2019	Y	5/21/2019	Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations www.fda.gov/regulatory-information/search-fda-guidance-documents/development-therapeutic-protein-biosimilars-comparative-analytical-assessment-and-other-quality
Publish final guidance on Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product	5/31/2019	Y	12/29/2016	Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-pharmacology-data-support-demonstration-biosimilarity-reference-product

Performance Enhancement Goal	Target Goal Date	On Time (Y/N)	Actual Completion Date	Comments
Publish final guidance on Nonproprietary Naming of Biological Products	5/31/2019	Y	1/12/2017	Nonproprietary Naming of Biological Products www.fda.gov/regulatory-information/search-fda-guidance-documents/nonproprietary-naming-biological-products-guidance-industry
Publish final guidance on Labeling for Biosimilar Products	5/31/2019	Y	7/18/2018	Labeling for Biosimilar Products www.fda.gov/regulatory-information/search-fda-guidance-documents/labeling-biosimilar-products-guidance-industry
Hold Public Meeting on Financial Transparency and Efficiency	6/30/2019	Y	6/7/2019	Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments 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 904(d) of FDARA, pertaining to BsUFA, 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.

Cause or Trend	Impact on FDA Commitments
BsUFA resubmitted original biosimilar applications cohort is small.	A single missed goal resulted in dropping below the performance goal.
BsUFA meeting cohort is small.	A single missed goal has a large impact on meeting management performance. For example, for certain meeting goals (e.g., the scheduling of BPD Type 1 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 timeframe.
Increasing resource-intensive meeting workload, common across all user fee programs, strained the same set of key staff within relevant offices/divisions.	Increasing workload contributed to the overall challenge of scheduling and completing meeting responses, preliminary responses, and meeting minutes on time. Logistical challenges also arise when scheduling necessary key individuals (e.g., signatories) for meetings within the goal dates.
Federal government shutdown	The federal government shutdown delayed publication of the FY19 update to the BsUFA Five-Year Financial Plan.

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Appendix D: FY 2019 Corrective Action Report

On August 18, 2017, FDARA (Public Law 115-52) 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. Title IX section 904 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 can improve and streamline the biosimilar product application 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 2019 Review Goal Performance

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Review Goals	• BsUFA resubmitted original biosimilar applications cohort is small. A single missed goal resulted in dropping below the performance goal.	• This reflects a single outlier scenario. FDA will continue to strive to meet all BsUFA review goals.
Procedural and Meeting Goals	• While the BsUFA meeting management cohort is small relative to other programs, increasing resource-intensive meeting workload, common across all user fee programs, strained the same set of key staff within relevant offices/divisions. • Moreover, missing a single goal in a small cohort has a large impact on performance.	• As part of a New Drugs Regulatory Program Modernization effort, FDA is executing a new drugs reorganization to better align and distribute resources.

FY 2019 Performance Enhancement Goal Performance

Goal Type	Circumstances and Trends Impacting Ability to Meet Goal Date	Corrective Action Plan
Reporting	• FDA published the FY 2019 BsUFA Five-Year Financial Plan Update in May 2019. Publication was delayed by the government shutdown.	• Barring another government shutdown, there should be no delay in publishing the FY 2020 update to the BsUFA Five-Year Financial Plan.

BsUFA Review Goals

The following section addresses section 904(d)(2)(B) of FDARA (section 744I(c)(2)(A) of the FD&C Act), which requires FDA to provide a justification for the determination of review goals missed during FY 2019 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) review of applications and supplements pertaining to biosimilar biological products and (2) meeting management and other procedural goals related to responses and notifications in the biosimilar review process.

This section includes all BsUFA II goals that were not met with required completion dates in FY 2019.

I. FY 2019 Review Goal Performance

A. Summary of Performance:

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

B. Justification:

The BsUFA resubmitted original biosimilar applications cohort is small. A single missed goal resulted in dropping below the performance goal.

C. FY 2020 Corrective Actions:

This was a single outlier scenario. FDA will continue to strive to meet all BsUFA review goal dates.

II. FY 2019 Procedural and Meeting Performance

A. Summary of Performance:

FDA missed the following meeting management goals:

- Meeting request response for BIA and BPD Types 1 and 3
- Meeting scheduling for BIA and BPD Types 1, 2, and 4
- Meeting preliminary response for BPD Type 3
- Meeting minutes for all meeting types

B. Justification:

Contributing factors in missing meeting management goals include the following:

- The BsUFA meeting 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 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 timeframe.

- Increasing resource-intensive meeting workload, common across all user fee programs, strained the same set of key staff within relevant offices/divisions and contributed to the overall challenge of scheduling and completing meeting responses, preliminary responses, and meeting minutes on time. Logistically, there are times when it can be challenging to schedule necessary key individuals (e.g., signatories) for meetings within the goal dates.

C. FY 2020 Corrective Actions:

FDA has engaged in a New Drugs Regulatory Program Modernization effort, which includes a reorganization of the Office of New Drugs within CDER. This ongoing effort, among other things, will re-align new drug therapeutic areas and flatten the organization. This will result in an increased number of signatories who can attend and sign off on formal meetings, which FDA expects will address some of the logistical scheduling issues. The reorganization also includes a centralization of regulatory health project managers, intended in part to promote and facilitate consistency in processes and performance. The reorganization will create greater efficiency and enhance FDA's ability to meet the BsUFA meeting goals.

BsUFA Performance Enhancement Goals

The following section addresses section 904(d)(2)(B) of FDARA (section 744I(c)(2)(B) of the FD&C Act), which requires FDA to provide, with respect to performance enhancement goals that were not achieved, a description of the efforts FDA has put in place to improve its ability to meet each such goal.

This section presents non-review performance goals cited in the Biosimilar Biological Product Reauthorization Performance Goals and Procedures for FY 2018 through FY 2022 with required completion dates in FY 2019. For the purposes of 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 2020 through FY 2022 will be covered in subsequent corrective action reports.

I. Reporting

A. *Summary of Performance:*

FDA missed the BsUFA goal for publishing an update to the BsUFA Five-Year Financial Plan.

B. *Justification:*

FDA published the FY 2019 BsUFA Five-Year Financial Plan Update in May 2019. Publication was delayed by the government shutdown.

C. *FY 2020 Corrective Actions:*

Assuming there is no government shutdown in 2020, there should not be a delay in publishing the FY 2020 update to the BsUFA Five-Year Financial Plan. In addition, FDA has concurrently been working to streamline internal processes to speed publishing and mitigate the risk of missing the timelines regardless of external factors (e.g., a government shutdown).

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Department of Health and Human Services
Food and Drug Administration

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