FY 2017

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) 2017 Biosimilar User Fee Act (BsUFA) Performance Report. On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA), which included the first authorization of BsUFA. 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.

FDA is dedicated to improving efficiency, quality, and predictability of the biosimilar biological product review. This report details FDA's preliminary performance for FY 2017, and finalizes performance results for FY 2016. While we have made substantial progress, there remains work to be done to ensure that we meet all BsUFA performance goals. In FY 2016, FDA met or exceeded 12 of our 20 performance goals and we expect to meet or exceed 11 of 19 performance goals that apply to the biosimilar submissions for the FY 2017 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 also are 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.

Scott Gottlieb, 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

CBER – Center for Biologics Evaluation and Research

CDER – Center for Drug Evaluation and Research

ETASU – Elements to Assure Safe Use

FDA – Food and Drug Administration

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 BsUFA program provides funding for the review of biosimilar biological products authorized under the Biologics Price Competition and Innovation Act of 2009 (BPCIA), enacted in March 2010. On July 9, 2012, the President signed into law FDASIA, which included the authorization of BsUFA. 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 fifth year of the BsUFA program. The report presents FDA's final performance in meeting BsUFA goals and commitments for FY 2016 and preliminary performance for FY 2017.

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 under BsUFA. Key highlights for this program during FY 2017 include the following:

- Of the 24 BsUFA goal categories, 20 applied to FY 2016 biosimilar submissions. FDA met or exceeded 12 of these 20 goals.

- FDA has the potential to meet or exceed 11 of the 19 goals that apply to the FY 2017 cohort once these actions are completed.

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Introduction

On July 9, 2012, the President signed into law FDASIA, which included the authorization of BsUFA. BsUFA authorizes FDA 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 2016 and preliminary performance for FY 2017. These data represent FDA's performance on submissions received and actions taken as of September 30, 2017. Final FDA performance for FY 2017 submissions will be presented in the FY 2018 BsUFA Performance Report and will include final actions for submissions still pending within the BsUFA goal date as of September 30, 2017. More detailed information on submissions and performance calculations, as well as definitions of key terms used in this report, are 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 or tentative approval letter
    - *Submission* applies to all of the above
- 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). Submissions that are received too late to be reviewed by the end of the fiscal year in which they are received are reported on in the subsequent fiscal year report after FDA takes an action, or when the review goal period expires.
- Unless otherwise noted, all performance data are as of September 30, 2017.
- Preliminary performance data for FY 2017 submissions are reported as the current percentage of submissions that have been reviewed within the review goal. The highest possible performance column shows the percent of reviews that will be completed on time if all non-overdue pending reviews are completed within goal.
- Appendix A includes the detailed final performance calculations for FY 2016 and preliminary performance calculations for FY 2017, including the number of submissions reviewed or acted on by the goal date and the number of overdue goals (acted on after the goal due date or currently pending past the goal due date). Performance is presented as percent on time. Preliminary performance excludes actions pending within the BsUFA goal date.

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 table below presents the goal timelines and the percentage of submissions that FDA committed to review within those goal timelines for FY 2013 through FY 2017. Additional information on BsUFA performance metrics and definitions for Biosimilar Biological Product Development (BPD) meeting types can be found in Appendix B.

FDA Performance Goal Targets

BsUFA Submission Type	Review Goal*	FY 13	FY 14	FY 15	FY 16	FY 17
Biosimilar Applications and Supplements						
Original Biosimilar Product Applications	10 months	70%	70%	80%	85%	90%
Resubmitted Original Biosimilar Applications	6 months	70%	70%	80%	85%	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	6 months	90%	90%	90%	90%	90%
Procedural Notifications						
Notification of Issues Identified During Review	74 days	90%	90%	90%	90%	90%
Notification of Planned Review Timeline	74 days	90%	90%	90%	90%	90%
Review of Proprietary Biosimilar Product Names (During BPD Phase)	180 days	90%	90%	90%	90%	90%
Review of Proprietary Biosimilar Product Names (with Application)	90 days	90%	90%	90%	90%	90%
Review of Proprietary Biosimilar Product Names (Resubmitted or Requests for Reconsideration)	60 days	90%	90%	90%	90%	90%
Procedural Responses						
Major Dispute Resolution	30 days	90%	90%	90%	90%	90%
Responses to Clinical Holds	30 days	90%	90%	90%	90%	90%
Special Protocol Assessments	45 days	70%	70%	80%	85%	90%
Meeting Management						
Meeting Requests: Initial Advisory Meeting	21 days	90%	90%	90%	90%	90%
Meeting Requests: BPD Type 1	14 days	90%	90%	90%	90%	90%
Meeting Requests: BPD Type 2	21 days	90%	90%	90%	90%	90%
Meeting Requests: BPD Type 3	21 days	90%	90%	90%	90%	90%
Meeting Requests: BPD Type 4	21 days	90%	90%	90%	90%	90%
Scheduling Meetings: Initial Advisory Meeting	90 days	70%	70%	80%	85%	90%
Scheduling Meetings: BPD Type 1	30 days	70%	70%	80%	85%	90%
Scheduling Meetings: BPD Type 2	75 days	70%	70%	80%	85%	90%
Scheduling Meetings: BPD Type 3	120 days	70%	70%	80%	85%	90%
Scheduling Meetings: BPD Type 4	60 days	70%	70%	80%	85%	90%
Provide Meeting Minutes: All Meeting Types	30 days	90%	90%	90%	90%	90%

* Review goal was formerly reported as “review-time goal.”

FY 2016 Final BsUFA Performance Summary

FY 2016 final BsUFA performance is summarized in the table below. The details of the calculations can be found in Appendix A.

Of the 24 BsUFA goal categories, 20 applied to FY 2016 biosimilar submissions. FDA met or exceeded 12 of these 20 goals.

FY 2016 Final Performance

BsUFA Submission Type	Review Goal	On Time	Performance Goal	Percent on Time	Goal Met
Biosimilar Application Review Goals					
Original Biosimilar Product Applications	10 months	3 of 3	85%	100%	Yes
Resubmitted Original Biosimilar Applications	6 months	1 of 1	85%	100%	Yes
Original Supplements with Clinical Data	10 months	0 of 0	90%	NA*	NA
Resubmitted Supplements with Clinical Data	6 months	0 of 0	90%	NA	NA
Manufacturing Supplements	6 months	7 of 7	90%	100%	Yes
Procedural Notifications					
Notification of Issues Identified during Review	74 days	3 of 3	90%	100%	Yes
Notification of Planned Review Timeline	74 days	3 of 3	90%	100%	Yes
Review of Proprietary Biosimilar Product Names (During BPD Phase)	180 days	14 of 14	90%	100%	Yes
Review of Proprietary Biosimilar Product Names (with Application)	90 days	9 of 10	90%	90%	Yes
Review of Proprietary Biosimilar Product Names (Resubmitted or Requests for Reconsideration)	60 days	0 of 0	90%	NA	NA
Procedural Responses					
Major Dispute Resolution	30 days	0 of 0	90%	NA	NA
Responses to Clinical Holds	30 days	3 of 3	90%	100%	Yes
Special Protocol Assessments	45 days	2 of 2	85%	100%	Yes
Meeting Management					
Meeting Requests: Initial Advisory Meeting	21 days	7 of 10	90%	70%	No
Meeting Requests: BPD Type 1	14 days	9 of 9	90%	100%	Yes
Meeting Requests: BPD Type 2	21 days	41 of 45	90%	91%	Yes
Meeting Requests: BPD Type 3	21 days	4 of 5	90%	80%	No
Meeting Requests: BPD Type 4	21 days	9 of 11	90%	82%	No
Scheduling Meetings: Initial Advisory Meeting	90 days	6 of 8	85%	75%	No
Scheduling Meetings: BPD Type 1	30 days	6 of 8	85%	75%	No
Scheduling Meetings: BPD Type 2	75 days	30 of 41	85%	73%	No
Scheduling Meetings: BPD Type 3	120 days	5 of 5	85%	100%	Yes
Scheduling Meetings: BPD Type 4	60 days	5 of 10	85%	50%	No
Provide Meeting Minutes: All Meeting Types	30 days	46 of 64	90%	72%	No

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

FY 2017 Preliminary BsUFA Performance Summary

The tables below present preliminary FY 2017 BsUFA performance.

- 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 2017 or were overdue as of September 30, 2017, out of all submissions received. This shows the share of the cohort that has had an action taken, whether or not it met the review goal.
- The *Percent on Time* column presents the percentage of actions completed that were within the review goal as of September 30, 2017. Actions that were pending and not yet past the goal date as of September 30, 2017, 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 11 of the 19 goals that apply to the FY 2017 cohort once these actions are completed.

FY 2017 Preliminary Performance

BsUFA Submission Type	Actions Completed	Review Goal	Performance Goal	Percent on Time	Highest Possible Performance
Biosimilar Applications and Supplements					
Original Biosimilar Product Applications	2 of 12 Complete	10 months	90%	100%	100%
Resubmitted Original Biosimilar Applications	2 of 2 Complete	6 months	90%	100%	100%
Original Supplements with Clinical Data	0 of 0 Complete	10 months	90%	NA	NA
Resubmitted Supplements with Clinical Data	0 of 0 Complete	6 months	90%	NA	NA
Manufacturing Supplements	2 of 7 Complete	6 months	90%	100%	100%
Procedural Notifications					
Notification of Issues Identified During Review	11 of 12 Complete	74 days	90%	100%	100%
Notification of Planned Review Timeline	11 of 12 Complete	74 days	90%	100%	100%
Review of Proprietary Biosimilar Product Names (During BPD Phase)	6 of 9 Complete	180 days	90%	100%	100%
Review of Proprietary Biosimilar Product Names (with Application)	15 of 15 Complete	90 days	90%	100%	100%
Review of Proprietary Biosimilar Product Names (Resubmitted or Requests for Reconsideration)	0 of 0 Complete	60 days	90%	NA	NA
Procedural Responses					
Major Dispute Resolution	0 of 0 Complete	30 days	90%	NA	NA
Responses to Clinical Holds	0 of 0 Complete	30 days	90%	NA	NA
Special Protocol Assessments	2 of 3 Complete	45 days	90%	100%	100%

FY 2017 Preliminary Performance (continued)

BsUFA Submission Type	Actions Completed	Review Goal	Performance Goal	Percent on Time	Highest Possible Performance
Meeting Management					
Meeting Requests: Initial Advisory Meeting	11 of 12 Complete	21 days	90%	55%	58%
Meeting Requests: BPD Type 1	4 of 4 Complete	14 days	90%	100%	100%
Meeting Requests: BPD Type 2	57 of 59 Complete	21 days	90%	95%	95%
Meeting Requests: BPD Type 3	3 of 3 Complete	21 days	90%	33%	33%
Meeting Requests: BPD Type 4	10 of 10 Complete	21 days	90%	80%	80%
Scheduling Meetings: Initial Advisory Meeting	8 of 9 Complete	90 days	90%	50%	56%
Scheduling Meetings: BPD Type 1	4 of 4 Complete	30 days	90%	50%	50%
Scheduling Meetings: BPD Type 2	45 of 48 Complete	75 days	90%	76%	77%
Scheduling Meetings: BPD Type 3	3 of 3 Complete	120 days	90%	100%	100%
Scheduling Meetings: BPD Type 4	10 of 10 Complete	60 days	90%	60%	60%
Provide Meeting Minutes: All Meeting Types	45 of 56 Complete	30 days	90%	84%	88%

BsUFA Workload

Review Workload: FY 2013 to FY 2017

The table below presents the review workload numbers from FY 2013 to FY 2017.

Review Workload for Applications and Submissions

BsUFA Workload	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Biosimilar Application Review Goals					
Original Biosimilar Product Applications	0	2	5	3*	12
Resubmitted Original Biosimilar Applications	0	0	0	1	2
Original Supplements with Clinical Data	0	0	0	0	0
Resubmitted Supplements with Clinical Data	0	0	0	0	0
Manufacturing Supplements	0	0	0	7*	7
Procedural Notifications					
Notification of Issues Identified During Review	0	2	5	3*	12
Notification of Planned Review Timeline	0	2	5	3*	12
Review of Proprietary Biosimilar Product Names (During BPD Phase)	3	3	5	14*	9
Review of Proprietary Biosimilar Product Names (with Application)	0	1	7	10	15
Review of Proprietary Biosimilar Product Names (Resubmitted or Requests for Reconsideration)	0	0	0	0	0
Procedural Responses					
Major Dispute Resolution	0	0	0	0	0
Responses to Clinical Holds	1	1	2	3	0
Special Protocol Assessments	0	2	1	2	3
Meeting Management					
Meeting Requests: Initial Advisory Meeting	4	11	3	10	12
Meeting Requests: BPD Type 1	0	1	3	9	4
Meeting Requests: BPD Type 2	21	30	48	45*	59
Meeting Requests: BPD Type 3	6	9	1	5	3
Meeting Requests: BPD Type 4	1	3	3	11	10
Scheduling Meetings: Initial Advisory Meeting	3	9	2	8	9
Scheduling Meetings: BPD Type 1	0	1	3	8	4
Scheduling Meetings: BPD Type 2	20	25	41	41*	48
Scheduling Meetings: BPD Type 3	6	9	1	5	3
Scheduling Meetings: BPD Type 4	1	3	3	10	10
Provide Meeting Minutes: All Meeting Types	29	44	47	64*	56

* Number modified from preliminary data reported in FY 2016.

Additional Reporting Requirements

Section 408 of FDASIA 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) that were approved by the Secretary; and
- An explanation of how FDA is managing the biological product review program to ensure that the user fees collected under part 2 are not used to review an application under section 351(k) of the PHS Act.

As of September 30, 2017, 22 351(k) applications were accepted for filing by FDA.

As of September 30, 2017, 32 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 periodic 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.

Appendices

Appendix A: Performance Calculations

The following tables detail the final performance for FY 2016 and preliminary performance for the FY 2017 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 goal or pending past the goal date) and the final *percent on time* (final performance with no actions pending within the BsUFA goal date). The FY 2016 performance data presented here have been updated from the preliminary performance information reported in the FY 2016 BsUFA Performance Report.

Biosimilar Applications and Supplements

Original Biosimilar Product Applications

Goal: Review and act on 90 percent of submissions within 10 months by FY 2017

Original Biosimilar Product Applications	FY 2016	FY 2017
Total Submissions (Workload)	**3**	**12**
Pending	0	10
On-Time	3	2
Overdue	0	0
Performance: % On-time	**100%**	**100%**
Highest Possible Performance:	**100%**	**100%**
BsUFA Goal: On-time Target %	**85%**	**90%**
Goal Met Status:	**Goal Met**	**Currently Meeting, Pending**

Resubmitted Original Biosimilar Applications

Goal: Review and act on 90 percent of submissions within 6 months by FY 2017

Resubmitted Original Biosimilar Applications	FY 2016	FY 2017
Total Submissions (Workload)	**1**	**2**
Pending	0	0
On-Time	1	2
Overdue	0	0
Performance: % On-time	**100%**	**100%**
Highest Possible Performance:	**100%**	**100%**
BsUFA Goal: On-time Target %	**85%**	**90%**
Goal Met Status:	**Goal Met**	**Will Meet Goal**

Manufacturing Supplements

Goal: Review and act on 90 percent of submissions within 6 months by FY 2017

Manufacturing Supplements	FY 2016	FY 2017
Total Submissions (Workload)	**7**	**7**
Pending	0	5
On-Time	7	2
Overdue	0	0
Performance: % On-time	**100%**	**100%**
Highest Possible Performance:	**100%**	**100%**
BsUFA Goal: On-time Target %	**90%**	**90%**
Goal Met Status:	**Goal Met**	**Currently Meeting, Pending**

Procedural Notifications

Notification of Issues Identified during Review

Goal: Review and act on 90 percent of submissions within 74 days

Notification of Issues Identified During Review	FY 2016	FY 2017
Total Submissions (Workload)	**3**	**12**
Pending	0	1
On-Time	3	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**

Notification of Planned Review Timeline

Goal: Planned review timelines are in 90 percent of the 74-day filing review notification letters

Notification of Planned Review Timeline	FY 2016	FY 2017
Total Submissions (Workload)	**3**	**12**
Pending	0	1
In 74-Day Letter	3	11
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**

Review of Proprietary Biosimilar Product Names (During BPD Phase)

Goal: Review and act on 90 percent of submissions within 180 days

Review of Proprietary Biosimilar Product Names (During BPD Phase)	FY 2016	FY 2017
Total Submissions (Workload)	**14**	**9**
Pending	0	3
On Time	14	6
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 Biosimilar Product Names (With Application)

Goal: Review and act on 90 percent of submissions within 90 days

Review of Proprietary Biosimilar Product Names (With Application)	FY 2016	FY 2017
Total Submissions (Workload)	**10**	**15**
Pending	0	0
On-Time	9	15
Overdue	1	0
Performance: % On-time	**90%**	**100%**
Highest Possible Performance:	**90%**	**100%**
BsUFA Goal: On-time Target %	**90%**	**90%**
Goal Met Status:	**Goal Met**	**Will Meet Goal**

Procedural Responses

Responses to Clinical Holds

Goal: Review and act on 90 percent of submissions within 30 days

Responses to Clinical Holds	FY 2016	FY 2017
Total Submissions (Workload)	**3**	**0**
Pending	0	0
On Time	3	0
Overdue	0	0
Current Performance: % On Time	**100%**	**NA**
Highest Possible Performance:	**100%**	**NA**
BsUFA Goal: On Time Target %	**90%**	**90%**
Goal Met Status:	**Goal Met**	**NA**

Special Protocol Assessments

Goal: Review and act on 90 percent of submissions within 45 days by FY 2017

Special Protocol Assessments	FY 2016	FY 2017
Total Submissions (Workload)	**2**	**3**
Pending	0	1
On-Time	2	2
Overdue	0	0
Performance: % On-time	**100%**	**100%**
Highest Possible Performance:	**100%**	**100%**
BsUFA Goal: On-time Target %	**85%**	**90%**
Goal Met Status:	**Goal Met**	**Currently Meeting, Pending**

Meeting Management[1]

Responses to Meeting Requests: Initial Advisory Meetings

Goal: Review and act on 90 percent of submissions within 21 days

Responses to Meeting Requests: Initial Advisory Meetings	FY 2016	FY 2017
Total Submissions (Workload)	**10**	**12**
Pending	0	1
On-Time	7	6
Overdue	3	5
Performance: % On-time	**70%**	**55%**
Highest Possible Performance:	**70%**	**58%**
BsUFA Goal: On-time Target %	**90%**	**90%**
Goal Met Status:	**Goal Not 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

Goal: Review and act on 90 percent of submissions within 14 days

Responses to Meeting Requests: BPD Type 1	FY 2016	FY 2017
Total Submissions (Workload)	**9**	**4**
Pending	0	0
On-Time	9	4
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**

Responses to Meeting Requests: BPD Type 2

Goal: Review and act on 90 percent of submissions within 21 days

Responses to Meeting Requests: BPD Type 2	FY 2016	FY 2017
Total Submissions (Workload)	**45**	**59**
Pending	0	2
On-Time	41	54
Overdue	4	3
Performance: % On-time	**91%**	**95%**
Highest Possible Performance:	**91%**	**95%**
BsUFA Goal: On-time Target %	**90%**	**90%**
Goal Met Status:	**Goal Met**	**Will Meet Goal**

Responses to Meeting Requests: BPD Type 3

Goal: Review and act on 90 percent of submissions within 21 days

Responses to Meeting Requests: BPD Type 3	FY 2016	FY 2017
Total Submissions (Workload)	**5**	**3**
Pending	0	0
On-Time	4	1
Overdue	1	2
Performance: % On-time	**80%**	**33%**
Highest Possible Performance:	**80%**	**33%**
BsUFA Goal: On-time Target %	**90%**	**90%**
Goal Met Status:	**Goal Not Met**	**Will Not Meet Goal**

Responses to Meeting Requests: BPD Type 4

Goal: Review and act on 90 percent of submissions within 21 days

Responses to Meeting Requests: BPD Type 4	FY 2016	FY 2017
Total Submissions (Workload)	**11**	**10**
Pending	0	0
On-Time	9	8
Overdue	2	2
Performance: % On-time	**82%**	**80%**
Highest Possible Performance:	**82%**	**80%**
BsUFA Goal: On-time Target %	**90%**	**90%**
Goal Met Status:	**Goal Not Met**	**Will Not Meet Goal**

Scheduling Meetings: Initial Advisory Meeting

Goal: Review and act on 90 percent of submissions within 90 days by FY 2017

Scheduling Meetings: Initial Advisory Meeting	FY 2016	FY 2017
Total Submissions (Workload)	**8**	**9**
Pending	0	1
On-Time	6	4
Overdue	2	4
Performance: % On-time	**75%**	**50%**
Highest Possible Performance:	**75%**	**56%**
BsUFA Goal: On-time Target %	**85%**	**90%**
Goal Met Status:	**Goal Not Met**	**Will Not Meet Goal**

Scheduling Meetings: BPD Type 1

Goal: Review and act on 90 percent of submissions within 30 days by FY 2017

Scheduling Meetings: BPD Type 1	FY 2016	FY 2017
Total Submissions (Workload)	**8**	**4**
Pending	0	0
On-Time	6	2
Overdue	2	2
Performance: % On-time	**75%**	**50%**
Highest Possible Performance:	**75%**	**50%**
BsUFA Goal: On-time Target %	**85%**	**90%**
Goal Met Status:	**Goal Not Met**	**Will Not Meet Goal**

Scheduling Meetings: BPD Type 2

Goal: Review and act on 90 percent of submissions within 75 days by FY 2017

Scheduling Meetings: BPD Type 2	FY 2016	FY 2017
Total Submissions (Workload)	**41**	**48**
Pending	0	3
On-Time	30	34
Overdue	11	11
Performance: % On-time	**73%**	**76%**
Highest Possible Performance:	**73%**	**77%**
BsUFA Goal: On-time Target %	**85%**	**90%**
Goal Met Status:	**Goal Not Met**	**Will Not Meet Goal**

Scheduling Meetings: BPD Type 3

Goal: Review and act on 90 percent of submissions within 120 days by FY 2017

Scheduling Meetings: BPD Type 3	FY 2016	FY 2017
Total Submissions (Workload)	**5**	**3**
Pending	0	0
On-Time	5	3
Overdue	0	0
Performance: % On-time	**100%**	**100%**
Highest Possible Performance:	**100%**	**100%**
BsUFA Goal: On-time Target %	**85%**	**90%**
Goal Met Status:	**Goal Met**	**Will Meet Goal**

Scheduling Meetings: BPD Type 4

Goal: Review and act on 90 percent of submissions within 60 days by FY 2017

Scheduling Meetings: BPD Type 4	FY 2016	FY 2017
Total Submissions (Workload)	**10**	**10**
Pending	0	0
On-Time	5	6
Overdue	5	4
Performance: % On-time	**50%**	**60%**
Highest Possible Performance:	**50%**	**60%**
BsUFA Goal: On-time Target %	**85%**	**90%**
Goal Met Status:	**Goal Not Met**	**Will Not Meet Goal**

Provide Meeting Minutes: All Meeting Types

Goal: Review and act on 90 percent of submissions within 30 days by FY 2017

Provide Meeting Minutes: All Meeting Types	FY 2016	FY 2017
Total Submissions (Workload)	**64**	**56**
Pending	0	11
On-Time	46	38
Overdue	18	7
Performance: % On-time	**72%**	**84%**
Highest Possible Performance:	**72%**	**88%**
BsUFA Goal: On-time Target %	**90%**	**90%**
Goal Met Status:	**Goal Not 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 for Major Amendments

   1. 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.
   2. A major amendment may include, for example, a major new clinical safety/efficacy 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.
   3. A major amendment to a manufacturing supplement submitted at any time during the review cycle may extend the goal date by 2 months.
   4. Only one extension can be given per review cycle.
   5. Consistent with the underlying principles articulated in the good review management principles 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.

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

D. A Biosimilar Initial Advisory 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 which 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 includes 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

[1] http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm079748.pdf

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 meeting to discuss the format and content of a biosimilar biological product application or supplement submitted under section 351(k) of the PHS Act.

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Department of Health and Human Services
Food and Drug Administration

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

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