BsUFA
Background and Reauthorization Process

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Andrew Kish
Director, Office of Program and Strategic Analysis
Center for Drug Evaluation and Research
Food and Drug Administration

Outline for this briefing

- BsUFA Background
- Financial Background and Fee Structure
- Workload and Performance
- Additional BsUFA II Commitments
- Reauthorization Process Overview

BsUFA Background

BsUFA is still a relatively new program.

- The Biologics Price Competition and Innovate Act of 2009 (BPCI Act) directed FDA to develop recommendations for a user fee program for 351(k) applications for FY 2013 – FY 2017.
- After consultation with regulated industry and public stakeholders, FDA transmitted recommendations to Congress on January 13th, 2012. The Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 included the first authorization of BsUFA.
- In 2011-2012, there were no marketing applications or products on the market, established drug development process or history related to biosimilar biological products.
- BsUFA is now entering its 9th year; PDUFA is entering its 28th year.
- Since its creation, BsUFA facilitated the approval of 28 biosimilar biological products for the American public.

BsUFA I to BsUFA II

BsUFA I (FDASIA) | *2013-2017*

- Referenced PDUFA fee amounts and included fees for products in the development phase in order to generate fee revenue to support FDA's review work during development and enable sponsors to have meetings with FDA early in development.
- Introduced predictable timelines and review process performance goals, primarily modeled on PDUFA, that increased over the course of BsUFA I.

BsUFA II (FDARA) | *2018-2022*

- Established an independent, efficient user fee structure based on program costs.
- Implemented a review program ("the Program") to promote the efficiency and effectiveness of the first review cycle and minimize the number of review cycles necessary for biosimilar approval.
- Added commitments to assess the Program, clarify the regulatory pathway, and enhance staff capacity.

Basic BsUFA construct

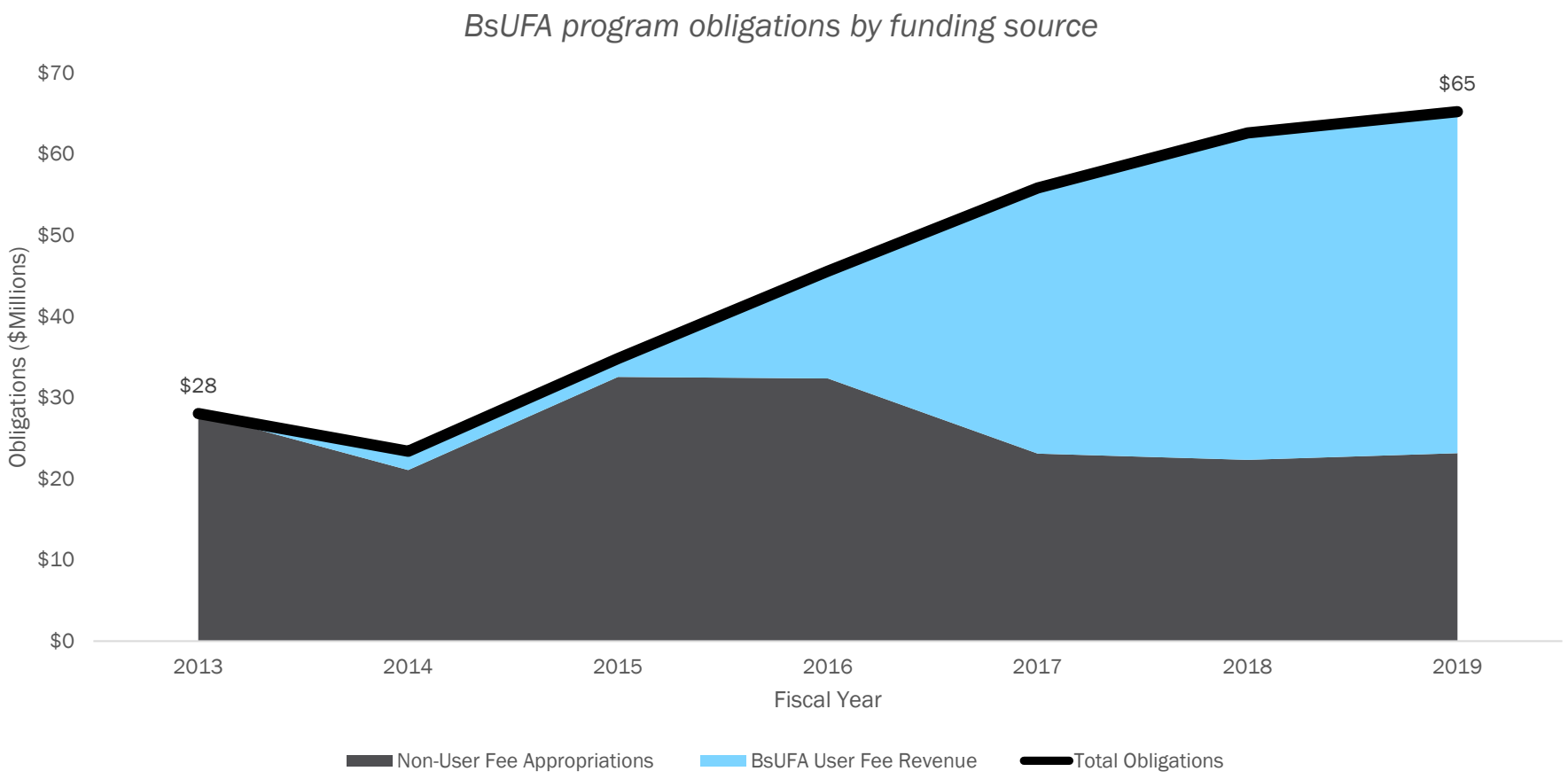
- Fee funds are added to appropriated funds and are intended to increase staffing and other resources to speed and enhance review process
- User fees pay for services that directly benefit fee payers*
- Fee discussions with industry focus on desired enhancements in terms of specific aspects of activities related to review of biosimilar biological products
    - What new or enhanced process will the FDA want or industry seek to include in the next 5 years?
    - What is technically feasible?
    - What resources are required to implement and sustain these enhancements?
    - No discussion of policy.
- Experience: *Devil is in the Details*

** OMB Circular A-25; direct benefit distinguishes user fees from tax*

Financial Background and Fee Structure

User fee revenue is critical to the program.

User fee revenue has outpaced budget authority available for the program



BsUFA user fee revenue funded **64% of the program** in FY2019.

Current Fee Structure

- FY 2021 target revenue is $42,493,000.
  - 28% collected from initial, annual, and reactivation fees for the BPD Program ($12,094,292 collected from an estimated 118 programs)
  - 33% collected from applications ($13,973,960 collected from an estimated 8 biosimilar biological product applications)
  - 39% collected from program fees for the BPD Program ($16,424,748 collected from an estimated 54 programs)

User Fee Type		FY2020	FY2021
Biosimilar Biological Product Development (BPD) Fee	Initial BPD	$117,987	$102,494
	Annual BPD	$117,987	$102,494
	Reactivation	$235,975	$204,988
Application Fee	Clinical Data Required	$1,746,745	$1,746,745
	Clinical Data Not Required	$873,373	$873,373
Program Fee		$304,162	$304,162

Workload and Performance

Fees support review work against a broad set of performance commitments.

28 specific review, procedural, and meeting management goals; in addition to other commitments

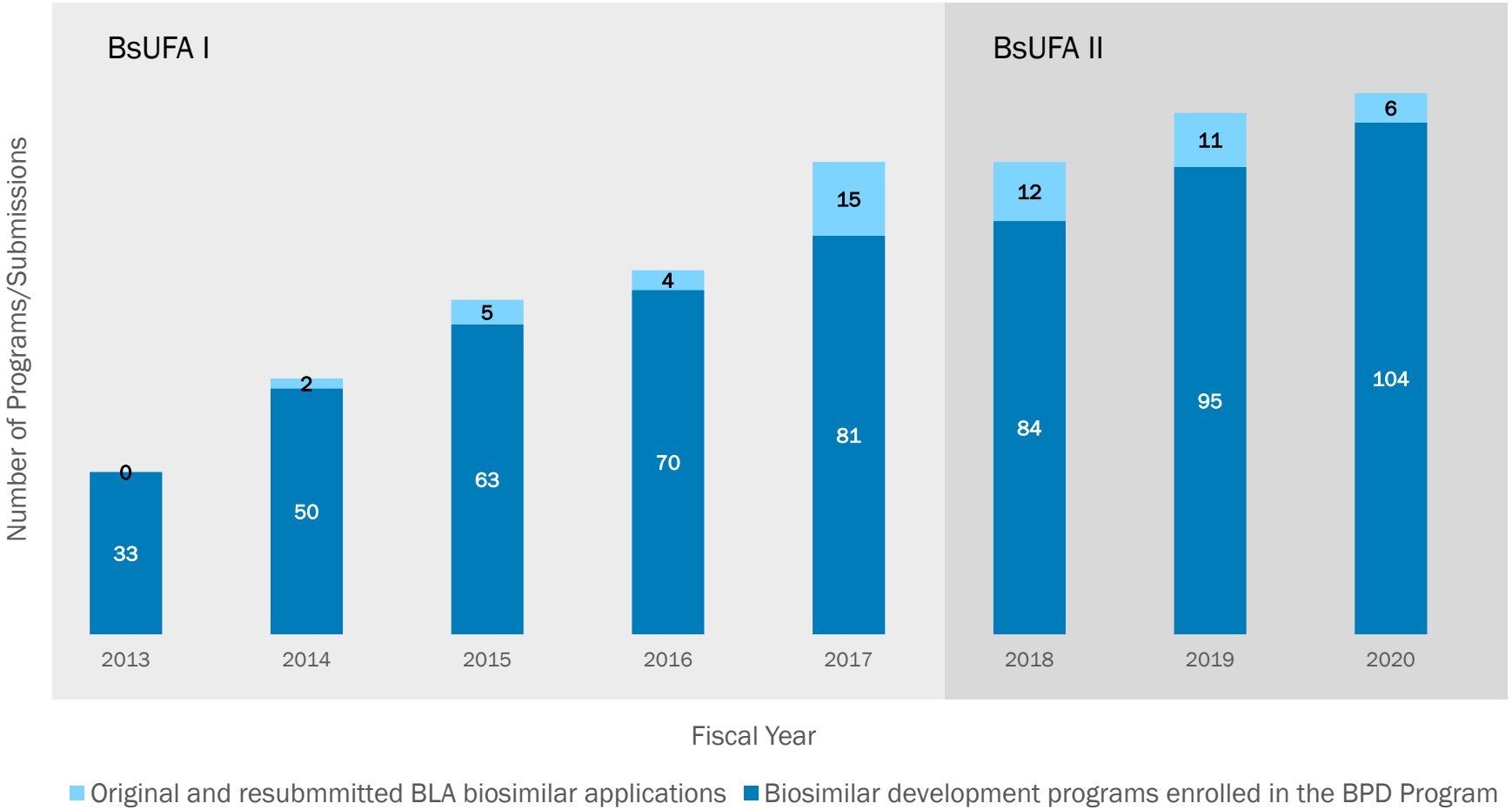
EXAMPLE	GOAL
Original & Resubmitted Original Biosimilar Biological Product Applications	90% of standard applications within 10 months of filing 90% of resubmitted standard applications within 6 months of receipt
Original & Resubmitted Supplements with Clinical Data	90% of standard supplements within 10 months of receipt 90% of resubmitted standard supplements within 6 months of receipt
Manufacturing Supplements	80% of prior approval supplements within 4 months of receipt (FY2020) 90% of non-prior approval supplements within 6 months of receipt
Major Dispute Resolution	90% of responses within 30 days of receipt
Clinical Hold Response	90% of clinical hold responses within 30 days of receipt
Special Protocol Assessments (SPA)	90% of SPAs and agreement requests within 45 days of receipt
Meeting Minutes	90% of minutes issued within 30 days of the meeting

FDA is on track to meet core review performance goals for FY2020.

Submission Type	Goal: Act on 90 Percent Within	Number Filed	FY 2020 Current Performance	Highest Possible Final Performance
Original Biosimilar BLAs	10 months of filing date	5		100%
Resubmitted Original Biosimilar BLAs	6 months	1		100%
Original Biosimilar Supplements With Clinical Data	10 months	2	100%	100%
Resubmitted Biosimilar Supplements With Clinical Data	6 months	1	100%	100%
Biosimilar Manufacturing Supplements Requiring Prior Approval *(Goal to act on 80 percent)*	4 months	30	96%	97%
Biosimilar Manufacturing Supplements Not Requiring Prior Approval	6 months	35	96%	98%
Biosimilar Labeling Supplements Requiring Prior Approval	6 months or 30 days	1	100%	100%
Biosimilar Labeling Supplements (CBE)	6 months or 30 days	1	100%	100%
Biosimilar Labeling Supplements (Unknown)	6 months or 30 days	2		100%

Biosimilar development is increasing.

Both BPD program enrollment and submitted biosimilar applications have increased from BsUFA I to BsUFA II.



Original and resubmitted applications by filing date. BPD Program by active participants.

Meeting management is a challenge.

CDER and CBER meeting management performance by FY

	Performance by Fiscal Year					
Meeting Management Goal	*2015*	*2016*	*2017*	*2018*	*2019*	*2020**
Biosimilar Initial Advisory Meeting Requests	100%	70%	50%	100%	73%	100%
Biosimilar Initial Advisory Meetings Scheduled	50%	75%	44%	60%	43%	100%
Biosimilar Initial Advisory Written Responses				100%		50%
Biosimilar Initial Advisory Preliminary Responses					86%	100%
BPD Type 1 Meeting Requests	100%	100%	100%	100%	89%	100%
BPD Type 1 Meetings Scheduled	67%	75%	50%	80%	75%	33%
BPD Type 2 Meeting Requests	98%	91%	95%	94%	97%	93%
BPD Type 2 Meetings Scheduled	49%	73%	76%	90%	71%	82%
BPD Type 2 Written Responses				90%	94%	61%
BPD Type 2 Preliminary Responses				87%	88%	84%
BPD Type 3 Meeting Requests	100%	80%	33%	100%	78%	100%
BPD Type 3 Meetings Scheduled	100%	100%	100%	100%	100%	100%
BPD Type 3 Preliminary Responses				100%	78%	100%
BPD Type 4 Meeting Requests	100%	82%	80%	100%	100%	88%
BPD Type 4 Meetings Scheduled	0%	50%	60%	83%	43%	63%
BPD Type 4 Preliminary Responses					100%	100%
Meeting Minutes for All Meeting Types	77%	72%	86%	91%	72%	90%

**FY2020 numbers are preliminary.*

Additional BsUFA II Commitments

We are on track to meet performance enhancement commitments.

In addition to the performance review goals under BsUFA II, FDA is implementing **over 50 actions to fulfill BsUFA II performance enhancement commitments.** These include:

14 new or updated pilots, programs or processes

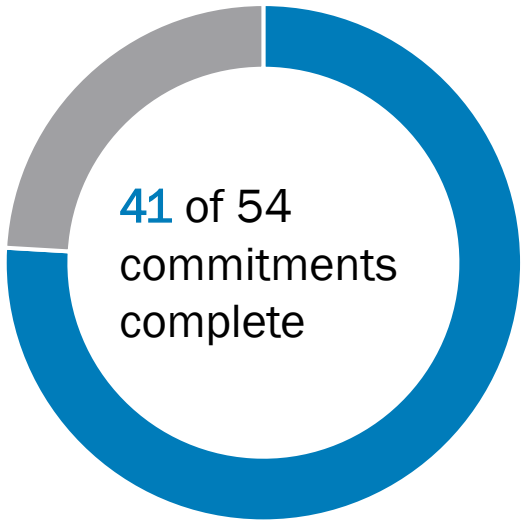
4 data/list postings to the public website

9 public meetings or public workshops

13 new or revised guidances

13 public reports

1 hiring goal



These performance enhancement commitments include…

- Ensuring Effectiveness of the Program
- Clarifying the 351(k) Regulatory Pathway
- Enhancing Capacity for Biosimilar Guidance, Review, and Communication
- Enhancing Management of User Fee Resources
- Improving FDA Hiring and Retention of Review Staff

Ensuring Effectiveness of the Program

Implementation of the Program

To promote the efficiency and effectiveness of the first review cycle and minimize the number of review cycles necessary for biosimilar approval, FDA implemented a review program ("the Program"). The Program introduces increased opportunities for communication with FDA via mid-cycle communications and late-cycle meetings.

Assessment of the Program

FDA contracted with an independent third-party to evaluate the impact of the Program on the efficiency and effectiveness of the first review cycle for biosimilars. FDA will host interim and final public meetings and publish interim and final public assessments.

Review of Proprietary Names to Reduce Medication Errors

To enhance patient safety, FDA committed to measures and associated performance goals to reduce medication errors related to look-alike and sound-alike proprietary names.

Updated Guidances

FDA updated the Good Review Management Principles and Practices (GRMP) guidance to ensure that it encompasses all review activities for biosimilar and interchangeable products. FDA revised draft guidance on Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants. FDA also updated guidance on Best Practices for Communication Between IND Sponsors and FDA During Drug Development.

Clarifying the 351(k) Regulatory Pathway

Draft Guidances

FDA published draft and final guidance on the following topics:

- Considerations in demonstrating interchangeability with a reference product,
- Statistical considerations for the analysis of analytic similarity data, and
- Processes and further considerations related to post-approval manufacturing changes for biosimilars.

Final Guidances

FDA published revised or finalized the following draft guidances:

- Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product,
- Nonproprietary Naming of Biological Products, and
- Labeling for Biosimilar Biological Products.

Enhancing Capacity for Biosimilar Guidance, Review, and Communication

Strengthen Staff Capacity

FDA strengthened staff capacity to:

- Develop **new regulations and guidance** to clarify scientific criteria for biosimilar development and approval to provide certainty to industry and other stakeholders related to key regulatory issues,
- Develop or revise **MaPPs, SOPPs, and review templates** to facilitate rapid update and application of new policies and guidance by review staff, and to develop and deliver timely comprehensive training to review staff,
- Deliver timely **information to the public** to improve public understanding of biosimilarity and interchangeability, and
- Deliver information concerning the date of first licensure and reference product exclusivity expiry date, to be included in the **Purple Book**.

Enhancing Management of User Fee Resources

Resource Capacity Planning and Modernized Time Reporting

FDA created and staffed a resource capacity planning capability to better predict future workload and understand associated resource demands. In addition, FDA developed a new capacity planning methodology that accounts for sustained increases in workload. FDA is also modernizing it's time reporting practices and systems in all Centers engaged in BsUFA work.

Financial Transparency and Efficiency

FDA contracted with an independent third party to evaluate BsUFA program resource management during FY 2018 to ensure user fee resources are administered, allocated, and reported in an efficient and transparent manner. FDA published BsUFA five-year financial plans each year and held annual public meetings starting in FY 2019 to discuss the plans, along with implementation of other management of user fee resources commitments.

Management of Carryover Balance

FDA committed to reducing the carryover balance. If FDA is unable to reduce the carryover balance to the specified amount, FDA will outline a plan to reduce the carryover balance and update the BsUFA five-year financial plan.

Improving FDA Hiring and Retention of Review Staff

Modernizing Hiring System Infrastructure

To modernize hiring system infrastructure and augment our system capacity, FDA deployed a position description library and is expecting to deploy a position-based management system.

Augmentation of Hiring Staff Capacity and Capability

Three contracts were awarded to vendors to provide continuous support for FDA's human resources capacity.

Establishment of a Dedicated Scientific Staffing Unit

FDA staffed a new HR unit focused on developing and implementing scientific staffing hiring strategies and plans.

Clear Goals for Biosimilar Biological Product Review Program Hiring

FDA established hiring goals and committed to reporting on the progress of these goals on the FDA website.

Comprehensive and Continuous Assessment of Hiring and Retention

FDA brought on third-party contractors to conduct an initial and interim assessment to better understand thus improve hiring practices.

Performance data and completed deliverables are available to the public

Completed BsUFA II deliverables can be found on FDA's website:

https://www.fda.gov/industry/biosimilar-user-fee-amendments/completed-bsufa-ii-deliverables

FDA released a new BsUFA performance dashboard that allows users to view and download current and historical performance data:

https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-bsufa-performance

BsUFA Reauthorization Process

BsUFA reauthorization process

BsUFA REAUTHORIZATION AND REPORTING REQUIREMENTS

(f) REAUTHORIZATION

(1) CONSULTATION - In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for the process for the review of biosimilar biological product applications for the first 5 fiscal years after fiscal year 2022, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with- (A) the Committee on Energy and Commerce of the House of Representatives; (B) the Committee on Health, Education, Labor, and Pensions of the Senate; (C) scientific and academic experts; (D) health care professionals; (E) representatives of patient and consumer advocacy groups; and (F) the regulated industry.

(2) PUBLIC REVIEW OF RECOMMENDATIONS - After negotiations with the regulated industry, the Secretary shall- (A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph; (B) publish such recommendations in the Federal Register; (C) provide for a period of 30 days for the public to provide written comments on such recommendations; (D) hold a meeting at which the public may present its views on such recommendations; and (E) after consideration of such public views and comments, revise such recommendations as necessary.

(3) TRANSMITTAL OF RECOMMENDATIONS - Not later than January 15, 2022, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

Priorities for BsUFA III

- Ensure stable funding for the program
- Enhance regulatory predictability and efficiency
- Enhance operational capabilities, efficiency, and agility
- Address information and scientific gaps to facilitate more efficient development

THANK YOU