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# BsUFA Background and Reauthorization Process

**Leah Christl**
Associate Director for Therapeutic Biologics
Office of New Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

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# Outline

- BsUFA Background
- Fee Structure
- Workload and Performance
- BsUFA I Accomplishments
- Reauthorization Process Overview
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# BACKGROUND

# BPCI Act directed FDA to develop recommendations for a new user fee program for 351(k) applications

- The Biologics Price Competition and Innovation Act (BPCI Act) amended the Federal Food, Drug, and Cosmetic Act to include 351(k) applications in the definition of "human drug application" enabling FDA to collect the same fees for 351(k) and 351(a) applications through September 2012.

- The BPCI Act required FDA to develop recommendations for Congress for a user fee program for 351(k) applications for FYs 2013 through 2017.
  - In developing recommendations, FDA consulted with regulated industry and public stakeholders, published the recommendations in the Federal Register, and held a public meeting to review the recommendations.
  - FDA transmitted the recommendations to Congress on January 13th, 2012.

- On July 9th, 2012 the president signed the Food and Drug Administration Safety and Innovation Act (FDASIA), which included the authorization of BsUFA. BsUFA allows FDA to collect user fees from the biosimilar biological product industry to supplement non-user fee appropriations the Agency spends on the process for the review of biosimilar biological product applications from October 2012 through September 2017.

# Basic BsUFA construct

- Fee funds are added to appropriated non-user fee funds and are intended to increase staffing and other resources to ensure predictable review process
- User fees pay for services that benefit fee payers
- Fee discussions with industry focus on desired enhancements in terms of specific aspects of activities in "process for the review of biosimilar biological product applications".
  - 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*

# BsUFA fees support FDA staff review work against an increasing performance level*

| Example: | 2013 | 2014 | 2015 | 2016 | 2017 |
|---|---|---|---|---|---|
| Original Biosimilar Applications | 70% in 10 months | 70% in 10 months | 80% in 10 months | 85% in 10 months | 90% in 10 months |
| Resubmitted Biosimilar Applications | 70% in 6 months | 70% in 6 months | 80% in 6 months | 85% in 6 months | 90% in 6 months |
| Original Supplements with Clinical Data | 90% in 10 months | | | | |
| Resubmitted Supplements with Clinical Data | 90% in 6 months | | | | |
| Manufacturing Supplements | 90% in 6 months | | | | |
| Special Protocol Assessments | 70% in 45 days | 70% in 45 days | 80% in 45 days | 85% in 45 days | 90% in 45 days |
| Clinical Hold Response | 90% within 30 days | | | | |
| Meeting Scheduling for Biosimilar Initial Advisory and BPD Type 1-4 Meetings | 70% | 70% | 80% | 85% | 90% |

*Not all commitments listed

# CURRENT FEE STRUCTURE

# Key principles guided BsUFA program design

1. Ensure sufficient review capacity to support biosimilar review to prevent unnecessary delays in the development and approval of 351(k) products.

2. Set 351(k) fees to be comparable to 351(a) fees because of comparable complexities.

3. Create a fee structure to ensure funds available to support critical development-phase review activities.

4. Avoid redirection of resources from 351(a) to 351(k) activities.

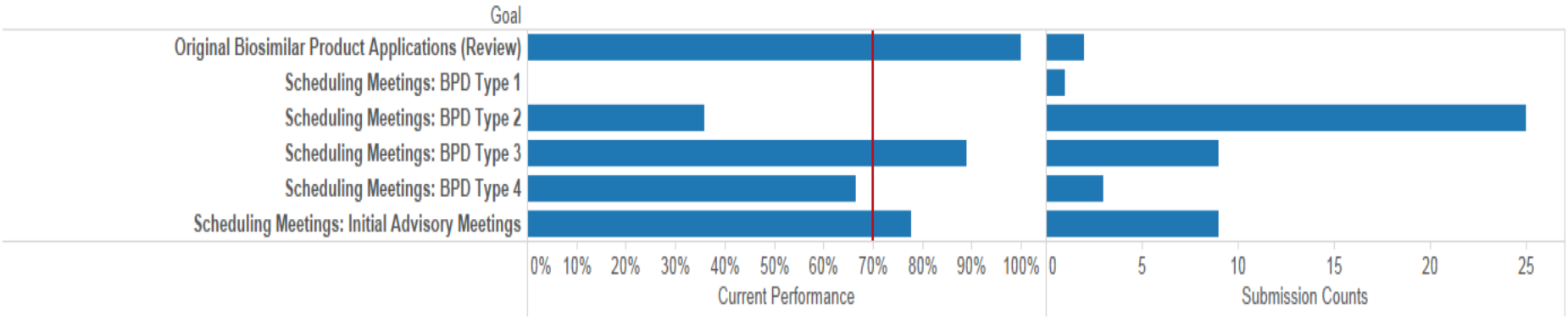
# Current Fee Structure

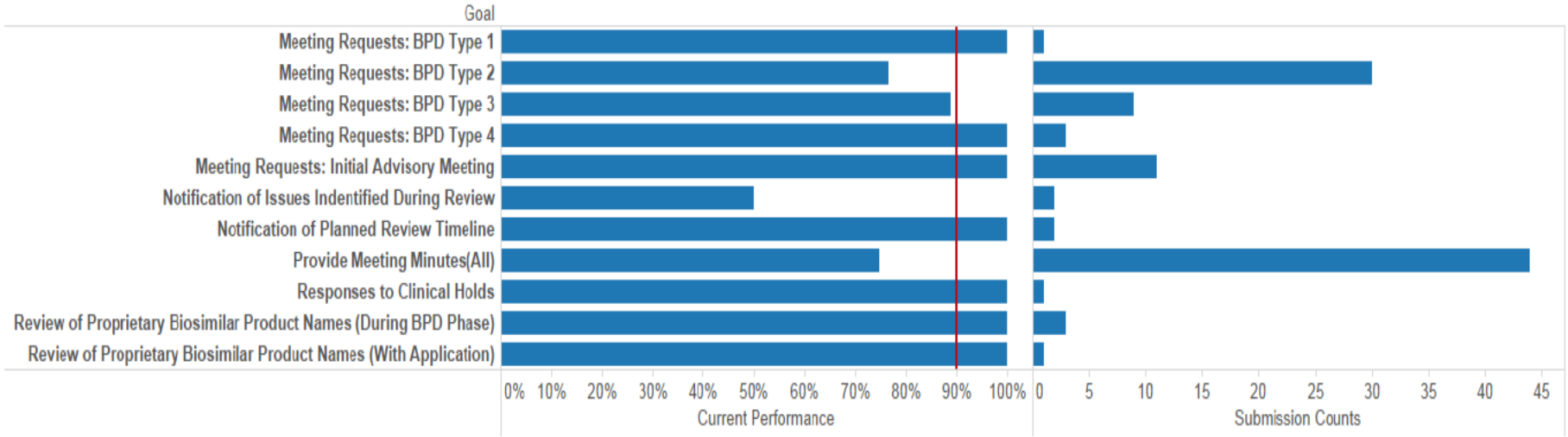
| Fee Type | Administration | Method | FY 2016 Amounts |
|---|---|---|---|
| Initial or annual biosimilar product development (BPD) fee | For each product in the BPD phase[1] | 10% of the human drug application fee | Initial/Annual BPD fee= $237,420 |
| Reactivation fee | For each product restarting development after previously discontinuing participation in the BPD program[2] | Twice the initial BPD fee | Reactivation = $474,840 |
| Application fee | For each biosimilar biological product application | Set equal to the human drug application fee, less sum of initial and annual BPD, and reactivation fee payments for the product | Application w/Clinical = $2,374,200<br>Application w/o Clinical = $1,187,100<br>Supplement w/Clinical = $1,187,100 |
| Establishment fee | Annual fee per biosimilar biological product establishment | Set equal to the prescription drug establishment fee | Establishments = $585,200 |
| Product fee | Annual fee per biosimilar biological product | Set equal to the prescription drug product fee | Products = $114,450 |

1. Initial BPD fee due at time of IND submission or within five days of FDA granting a BPD meeting request. Annual BPD fee begins in the next fiscal year after a sponsor pays the initial BPD or reactivation fee.
2. Reactivation fee applies if sponsor rejoins the BPD Program for a product after withdrawing. Fee is due at time of IND submission or within five days of FDA granting a BPD meeting request.

# PERFORMANCE & WORKLOAD

# FY 2014 BsUFA review, meeting, and procedural performance




CDER & CBER combined FY14 current and potential performance as published in FY14 Performance Report

# ADDITIONAL BSUFA I ACCOMPLISHMENTS

# Implementation Committees

- FDA established three committees to ensure consistency in FDA's regulatory approach and guidance to sponsors regarding development programs for
  - proposed biosimilar biological products intended for submission under section 351(k) of the PHS Act, and
  - related issues.
- The committees charged with discussing and coordinating issues related to biosimilars are:
  - CDER/CBER Biosimilar Implementation Committee
  - CDER Biosimilar Review Committee
  - CBER Biosimilar Review Committee

# OND Therapeutic Biologics and Biosimilars Staff (TBBS)

- Housed in the Office of New Drugs (OND) Immediate Office
- Ensure consistency in regulatory approach and in advice provided to sponsors regarding development programs for proposed biosimilar products, applications submitted under 351(k) of the PHS Act and issues related to the implementation of the BPCI Act of 2009
- Central point of contact for OND and other CDER staff for biosimilars, therapeutic biologics, and follow-on versions of complex protein products and other complex products
- Develop policy, procedures and staff training to consistently implement the BPCI Act
- Manage CDER's Biosimilar Review Committee

# Public Meetings

- FDA held two public meetings on the BPCI Act
  - November 2-3, 2010: to obtain input on specific issues and challenges associated with the implementation of the BPCI Act
    - The comments received informed the development of the first three draft guidances published in February 2012
  - May 11, 2012: to obtain input on recently issued draft guidances relating to the development of biosimilar products and to solicit public input regarding topics for future policies on biosimilars

# Guidance Issued

- FDA has issued a total of 8 guidance documents to date related to the implementation of the BPCI Act.
- FDA issued final guidance documents:
  - Scientific Considerations in Demonstrating Biosimilarity to a Reference Product (issued April 2015)
  - Quality Considerations in Demonstrating Biosimilarity to a Reference Product (issued April 2015)
  - Guidance for Industry on Biosimilars: Q & As Regarding Implementation of the BPCI Act of 2009 (issued April 2015
  - Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants (issued November 2015)
- FDA issued additional draft guidance:
  - Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product (issued May 2014)
  - Reference Product Exclusivity for Biological Products Filed under 351(a) of the PHS Act (issued August 2014)
  - Biosimilars: Additional Questions and Answers Regarding Implementation of the BPCI Act of 2009 (issued May 2015)
  - Nonproprietary Naming of Biological Products (issued August 2015)

# Additional Guidance Plans

- FDA has identified additional guidances that the agency plans to publish:
  - Considerations in Demonstrating Interchangeability to a Reference Product
  - Labeling for Biosimilar Biological Products
  - Statistical Approaches to Evaluation of Analytical Similarity Data to Support a Demonstration of Biosimilarity

# BsUFA REAUTHORIZATION PROCESS

# BsUFA Reauthorization Involves Significant Consultation

## BsUFA REAUTHORIZATION and REPORTING REQUIREMENTS

**(e) 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 application for the first 5 fiscal year after fiscal year 2017, and for the reauthorization of this part 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, 2017, 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.

# BsUFA I Assumptions

- Predictable workload with consistent number of BPD programs and meetings, along with more 351(k) applications early in BsUFA I
  - 8 BPD products on average with no more than 11 at one time
  - 1-2 BPD meetings a year per sponsor, 16 total on average
  - 13 351(k)s through end of FY '15
- Resources required for reviewing 351(k) development programs and applications similar to PDUFA resource requirements
- Ability to recruit and hire qualified staff for BsUFA program

# Priorities for BsUFA II

- Review BsUFA program to further increase the quality and predictability of product development and review
- Revisit workload assumptions from BsUFA I to ensure accurate resourcing
- Ensure financial soundness through fair and efficient fee structure enhancements – including financial management and reporting system enhancements
- Recruiting and retaining critical staff for biosimilar product development and 351(k) BLA review

# Thank you!