Navigating the World of Biosimilar User Fees

Beena Alex, MPH, MBA
Lead Management Analyst
Division of User Fee Management and Budget Formulation, Office of Management
CDER | US FDA

Objectives

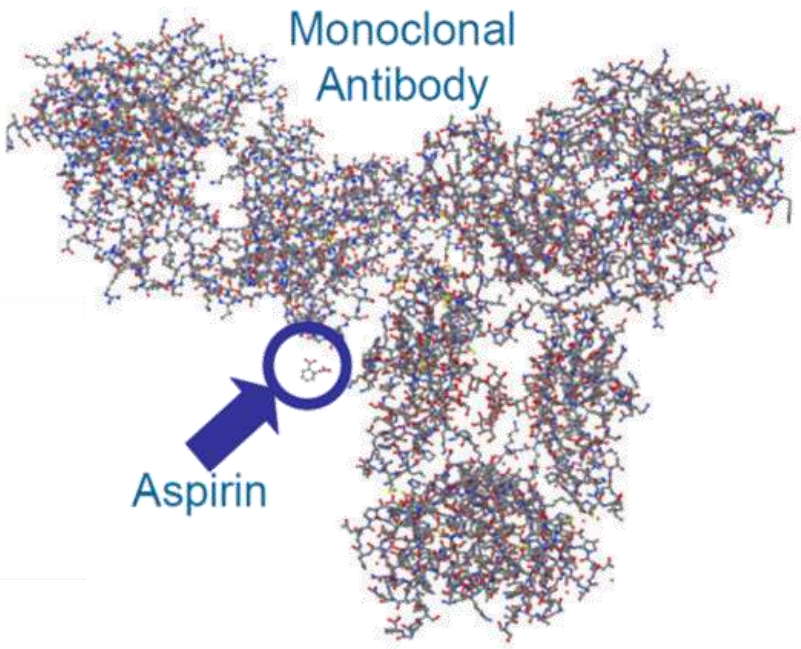
- Background
- Fee Structure
- Waiver and Refunds
- Failure to Pay Fees
- Reminders and Resources

BsUFA Background

Biologics Price Competition and Innovation (BPCI) Act	•March 23, 2010 •Amended the Public Health Service (PHS) Act to allow for an abbreviated licensure pathway [(351(k)] to biological products shown to be biosimilar or interchangeable with an FDA licensed reference product
Food and Drug Administration Safety and Innovation Act (FDASIA)	•July 9, 2012 •Biosimilar User Fee Act of 2012 (BsUFA) •Authorizes FDA to assess and collect fees for biosimilar biological products under §744H of the Food, Drug and Cosmetic Act (FD&C Act) •Fiscal Years 2013 through 2017
Food and Drug Administration Reauthorization Act (FDARA)	•August 18, 2017 •Biosimilar User Fee Amendments of 2017 (BsUFA II) •Fiscal Years 2018 through 2022 •Independent fee structure

What is a Biological Product?

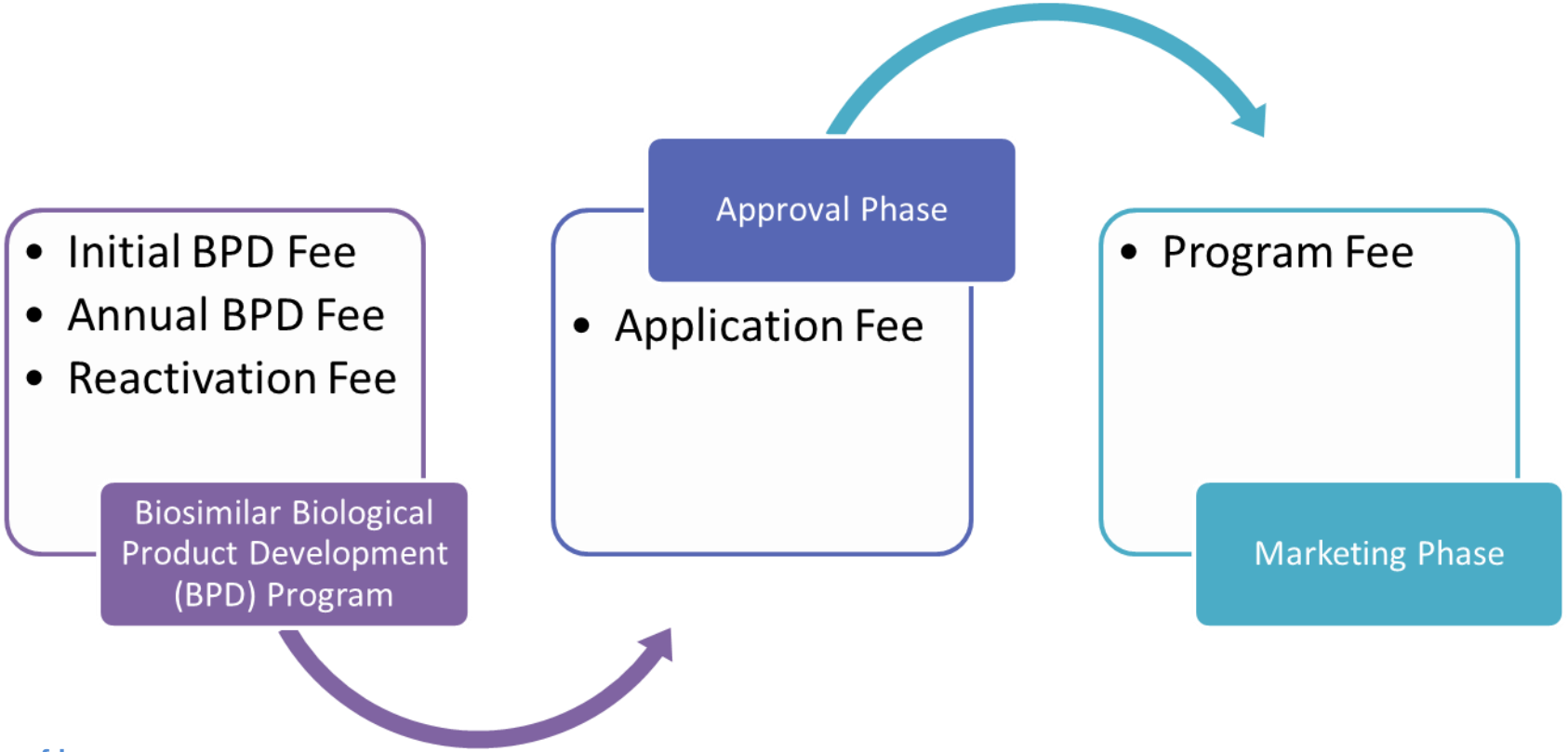
- Large complex molecule
- Generally of high molecular weight
- Generally made from human and/or animal materials
- Includes vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and proteins (except any chemically synthesized polypeptides)



What is a Biosimilar?

- A biological product that is “highly similar” or “interchangeable” to a US licensed reference biological product
- **“Biosimilar”** or “biosimilarity”
  - **Highly similar to the reference product** not withstanding minor differences in clinically inactive components
  - **No clinically meaningful differences between the biological product and the reference product** in terms of safety, purity, and potency of the product
- **“Interchangeable”** or “interchangeability”
  - **Biological product may be substituted for the reference product** without the intervention of the health care provider who prescribed the reference product

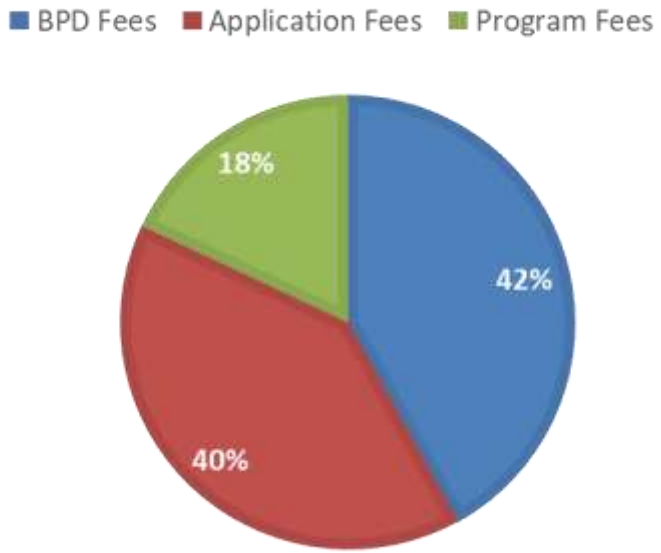
Fee Structure



FY 2019 BsUFA Fees

- Fees published annually in the Federal Register
- FY 2019 target revenue: $38,847,000

Fee Type		FY 2019
BPD	Initial	$185,409
	Annual	$185,409
	Reactivation	$370,818
Application	w/Clinical Data	$1,746,745
	w/o Clinical Data	$873,373
Program		$304,162



Initial BPD Fee

- One time fee to join the BPD program for a biosimilar product in development
- No fee for a Biosimilar Initial Advisory (BIA) meeting

Triggered by:	Fee Due:
BPD meeting request granted for a product (BPD Type 1, 2, 3 or 4 meeting)	Not later than 5 calendar days after the meeting request is granted
IND submission	At the time of submission

Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products (Draft Guidance, June 2018)

Annual BPD Fee

- Annual fee owed by sponsors who are in the BPD program
- Obligation begins in the next fiscal year
  - FY 2020: October 1, 2019 through September 30, 2020
- One fee per pre-IND/IND
- Invoices issued in August and December of each year
- Payment is due by the first business day on or after October 1 of each fiscal year

Annual BPD Fee Exceptions

- Discontinue participation in the BPD program **by August 1 of previous fiscal year**
- Submit a marketing application for a biosimilar product that is accepted for filing

Reactivation Fee

- Fee to re-engage with FDA after discontinuing participation in the BPD program

Triggered by:	Fee Due:
BPD meeting request granted for a product (BPD Type 1, 2, 3, or 4 meeting)	Not later than 5 calendar days after the meeting request is granted
IND submission	At the time of submission

Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products (Draft Guidance, June 2018)

✓ Annual BPD fee obligation resumes in the next fiscal year

Application Fee

FULL APPLICATION FEE

- Clinical data **are required** for approval

HALF APPLICATION FEE

- Clinical data **are not required** for approval

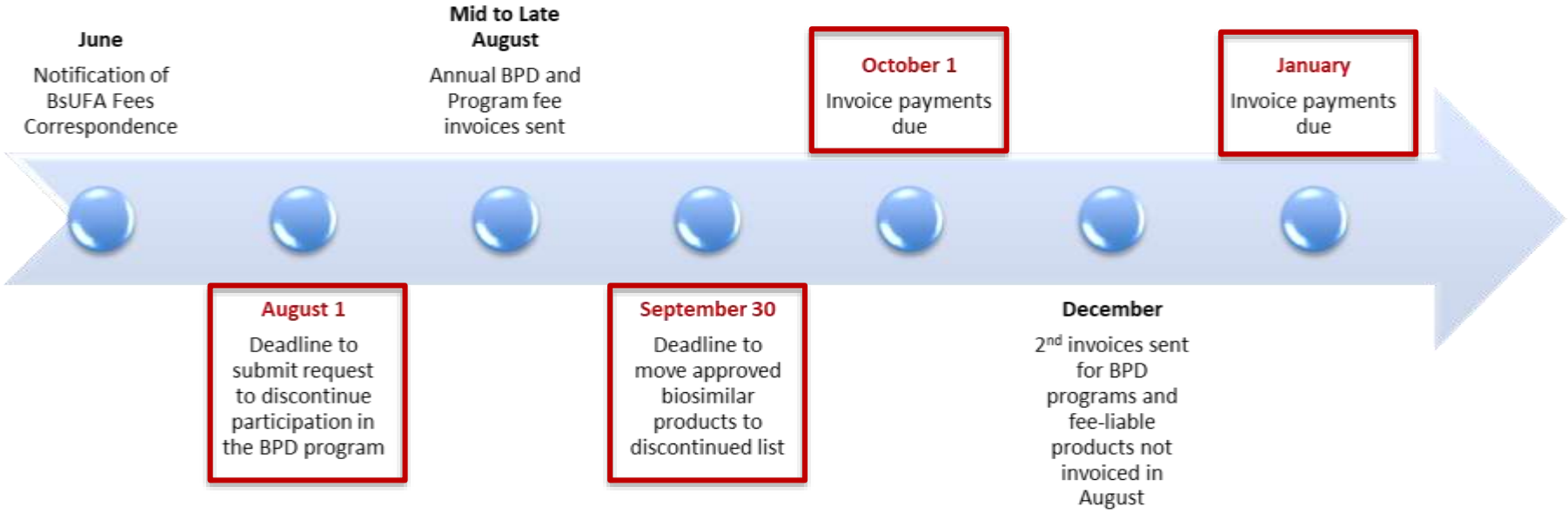
Program Fee

- Assessed annually
- Maximum of 5 program fees per application
- Invoices issued in August and December of each year
- Payment is due by the first business day on or after October 1 of each fiscal year

Therapeutic Biosimilar List

- Contains all user fee eligible and discontinued (not marketed) products
- List is available on the BsUFA website under “Related Info”
- Companies are responsible for notifying the User Fee staff of any discrepancies
- Deadline to make changes is September 30

Invoice Timeline



Small Business Waiver - Criteria

- An applicant must meet all of the following criteria:
  - The applicant employs fewer than 500 employees, **including employees of affiliates**
  - The applicant does not have a drug product that has been approved under a **human drug application or a biosimilar application** and introduced or delivered for introduction into interstate commerce
  - The applicant, **including its affiliates**, is submitting its first biosimilar application

Small Business Waiver - Timing

- Complete Form FDA 3971, Small Business Waiver and Refund Request
- Submit to CDERCollections@fda.hhs.gov at least 4 months prior to submission of the biosimilar application
- Expires after 1 year
  - Need to resubmit after 1 year or if the application is Refuse To File

Refunds

No refunds for:

- Initial BPD fee
- Reactivation fee

Refunds may be requested for:

- Annual BPD fee
- Application fee
- Program fee

Waivers and Refunds – 180 Day Rule

- Formal written request should be submitted not later than 180 days after such a fee is due
- Submit Form FDA 3913, User Fee Payment Refund Request
- Submit to CDERCollections@fda.hhs.gov

What Can Go Wrong?

- Failure to pay BPD fees (initial, annual, and reactivation fees)
  - No BPD meetings related to the product
  - No receipt of IND application
  - Financial hold
  - No acceptance of any biosimilar applications or supplements
- Failure to pay application and program fees
  - No acceptance of any biosimilar applications or supplements

Important Reminders

- August 1 = deadline to discontinue participation from the BPD program
- September 30 = deadline to move an approved biosimilar product to the discontinued list
- October 1 = invoice payments due
- 180 calendar days after such fee is due to submit a waiver or refund request

Additional Resources

Guidance: Assessing User Fees Under the Biosimilar User Fee Amendments of 2017

Therapeutic Biosimilar Biological Products List

- Contains all user fee-eligible and discontinued (not marketed) products

BsUFA Website

Contact Information

Center for Drug Evaluation and Research

Office of Management

Division of User Fee Management and Budget Formulation

CDERCollections@fda.hhs.gov

301-796-7900

Challenge Question

- A sponsor pays the initial BPD fee on September 28, 2019 and enters the BPD program. Does the sponsor owe a FY 2020 annual BPD fee?


FDA
U.S. FOOD & DRUG
ADMINISTRATION