GDUFA | BsUFA User Fees Updates

Division of User Fee Management and Budget Formulation
OM | CDER| US FDA
September 6, 2018

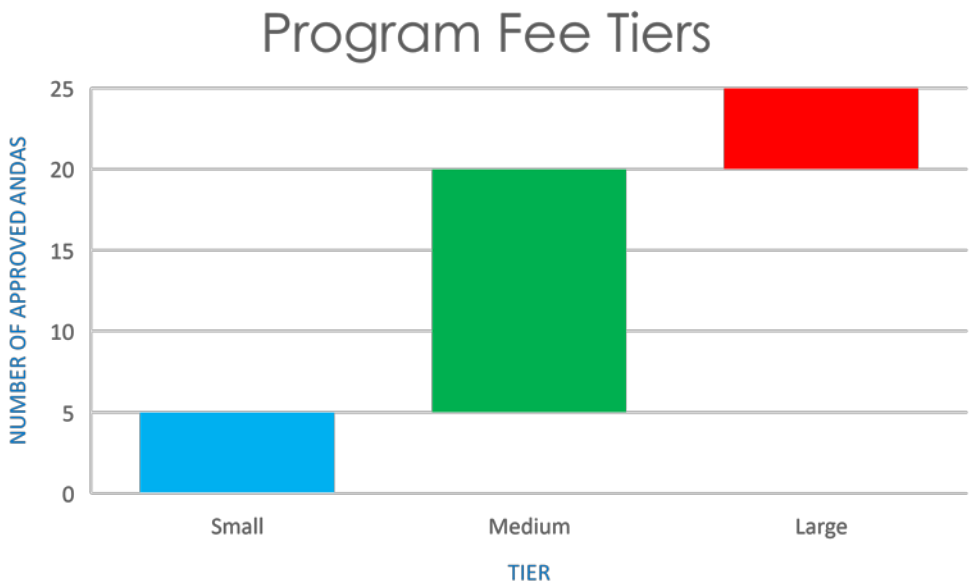
AGENDA TOPICS

- GDUFA Fees
- Program Fee/Portal
- Upcoming Timeline
- ANDA Submissions/Withdrawals
- Facility Fee
- Contract Manufacturing Organization
- Facility Fee vs Self ID
- Facility Withdrawals
- Helpful Resources

What are the new fees?

Program fee is assessed annually for each company and its affiliates depending on the number of **approved** ANDAs in their portfolio.

- **Small**: 5 or fewer
- **Medium**: 6 to 19
- **Large**: 20 or more



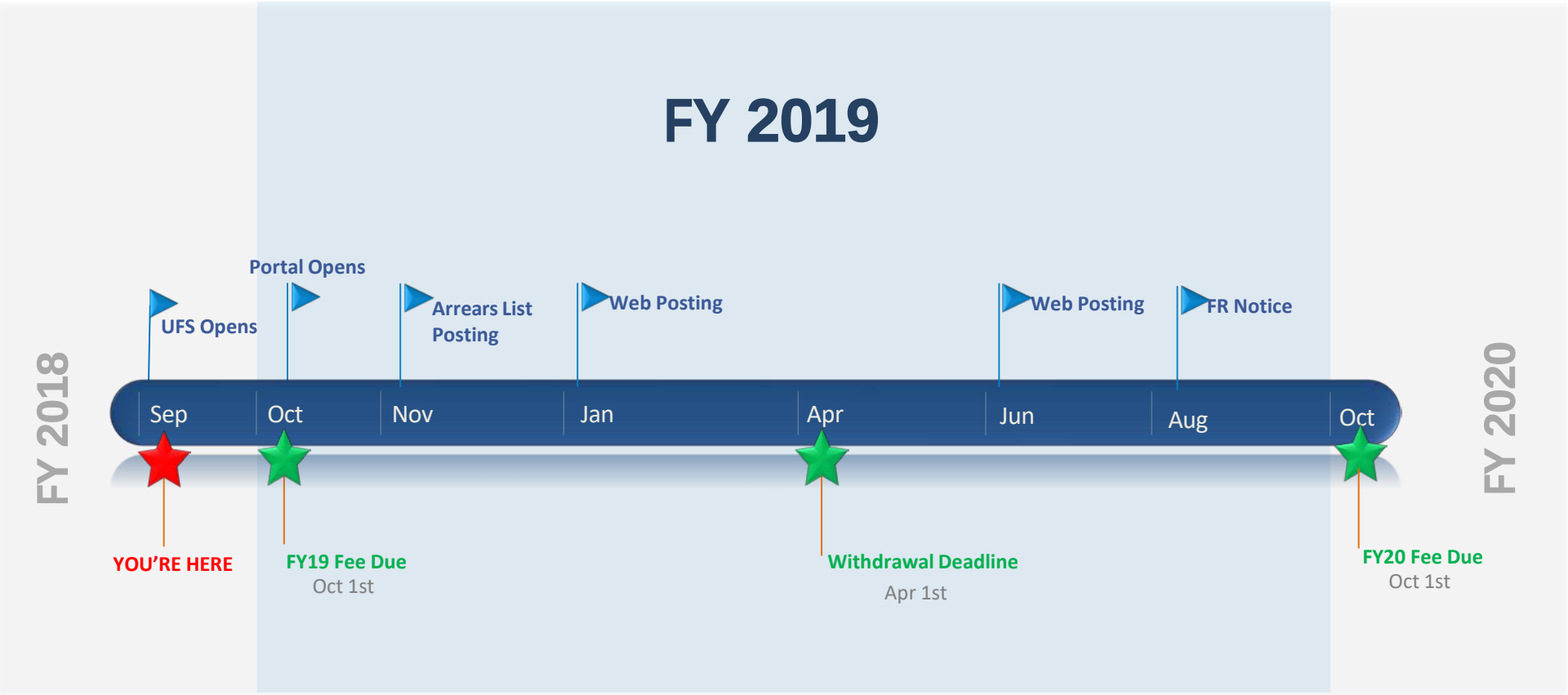
FDA CDER Direct NexGen Collaboration Portal

Purpose: Industry can submit portfolio information to FDA for purposes of determining the parent company's Generic Drug Applicant Program Fee tier.

Launch Date: October 1, 2018

Link: https://edm.fda.gov

UPCOMING TIMELINE



ANDA SUBMISSIONS/WITHDRAWALS

Submission FDA Received Date

- Start of FY19: **Monday, October 1, 2018**
- FY Cross Over: Received Date is when the submission is received by FDA via Electronic Submissions Gateway (ESG)
- Updated 356h: Include applicant DUNS field

Withdrawal request

- Submit via the gateway

FACILITY FEE ASSESSMENTS

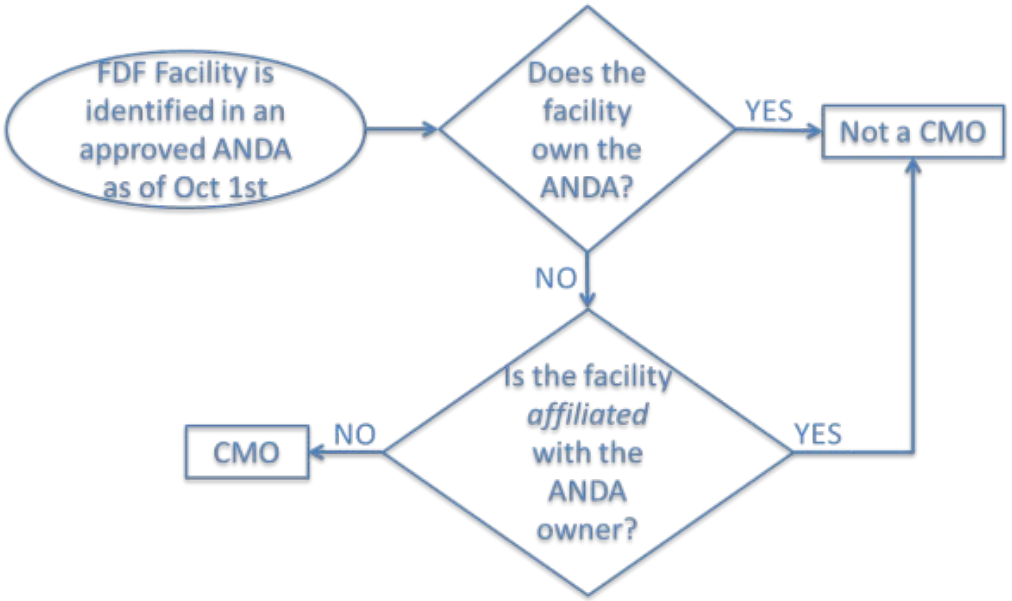
- Facility fees are assessed for facilities listed in at least one **approved** generic drug submission on fee due date.
  - Dual operations (API & FDF) will incur only an FDF fee.

- **No fees** are required for:
  - Facilities listed in pending generic drug submissions only
  - PET manufacturers
  - State/federal manufacturers of non-commercial products

CONTRACT MANUFACTURING ORGANIZATION (CMO)

- Some FDFs meet the statutory definition of a CMO.
- CMO fee is one-third the fee assessed to an FDF facility.

Am I a CMO?



FACILITY FEE VS SELF-IDENTIFICATION

- Facility fee assessments are **not** triggered by the absence or presence of a facility in the self-identification data.

How to avoid a facility fee?

- A facility will stop incurring a facility fee when it is withdrawn from **all** generic drug submissions **before** the fee due date.
  - Annual facility fees are **not** prorated.
  - Facility withdrawal process is outlined in the most current guidance document.

FACILITY FEE - FRIENDLY REMINDERS

- ✓ Form FDA 356h/Establishment Information
  - ✓ Quality Section
- ✓ Be mindful of wire transfer fees
- ✓ "Guidance For Industry" documents

GDUFA TIMELINE

April 1st

- ✓ Deadline to submit ANDA withdrawals for the upcoming FY

Early August

- ✓ Federal Register Notice posting

Early September

- ✓ Web posting with program tiers
- ✓ iStore open for early annual payments

October 1st

- ✓ Annual payments due date

HELPFUL RESOURCES

- ✓ GDUFA user fees information and updates:
  www.fda.gov/gdufa
  - ➢ GDUFA guidance documents found under **"Related Info"** section
- ✓ General user fee-related questions:
  CDERCollections@fda.hhs.gov
- ✓ Self-identification Technical Support:
  CDEReFacility@fda.hhs.gov
- ✓ Program Fee Portal Technical Support:
  EDMSupport@fda.hhs.gov
- ✓ FDA Listserv:
  http://go.fda.gov/subscriptionmanagement

BsUFA Updates

- Fee Structure
- Therapeutic Biosimilar Biological Products List
- Fee Rates
- Annual Survey
- Waivers and Refunds
- Helpful Resources

FEE STRUCTURE

Biosimilar Biological Product Development (BPD) Program

- Initial BPD Fee
- Annual BPD Fee
- Reactivation Fee

Approval Phase

- Application Fee

Marketing Phase

- Program Fee

INITIAL BPD FEE

- One time fee assessed to a sponsor to enter the BPD program for a biosimilar biological product in development

- Triggered by
  - A BPD meeting request that is granted for a product
  - Submission of a clinical protocol for an IND intended to support a biosimilar biological product application for a product

- Not later than 5 calendar days after the meeting granted letter is sent to the sponsor

- The date of submission of an IND

ANNUAL BPD FEE

- Once a sponsor enters the BPD program for a product, the sponsor will owe an annual BPD fee for such product beginning in the next fiscal year
- One fee per pre-IND/IND

- Issued August 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 for a biosimilar biological product under development
  - Formal written request must be submitted by **August 1** of the preceding fiscal year
  - "Inactivation" of the IND does not exempt the sponsor from the annual BPD fee obligation

- Submit a marketing application for a biosimilar biological product that was accepted for filing

REACTIVATION FEE

- If a sponsor wishes to re-engage with FDA for a product that has discontinued participation in the BPD program, the sponsor must reenter the program and pay a reactivation fee.

- Twice the initial BPD fee

DUE

- Not later than 5 calendar days after the meeting granted letter is sent to the sponsor

- The date of submission of an IND

✓ Annual BPD fee obligation resumes in the next fiscal year

APPLICATION FEE

FULL APPLICATION FEE

Clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness **are required** for approval

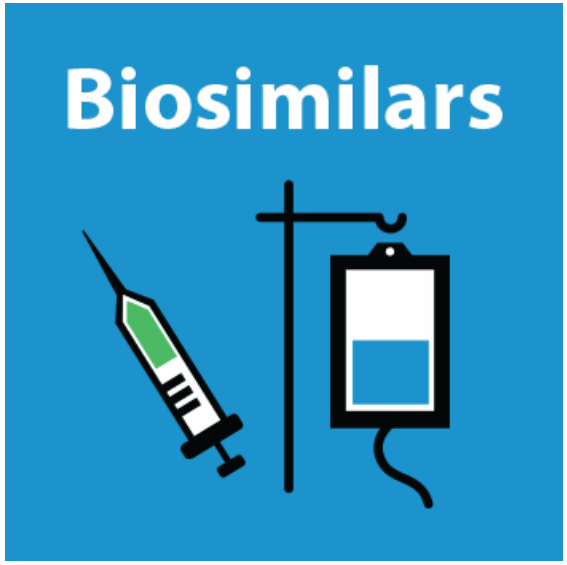
HALF APPLICATION FEE

Clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness **are not required** for approval

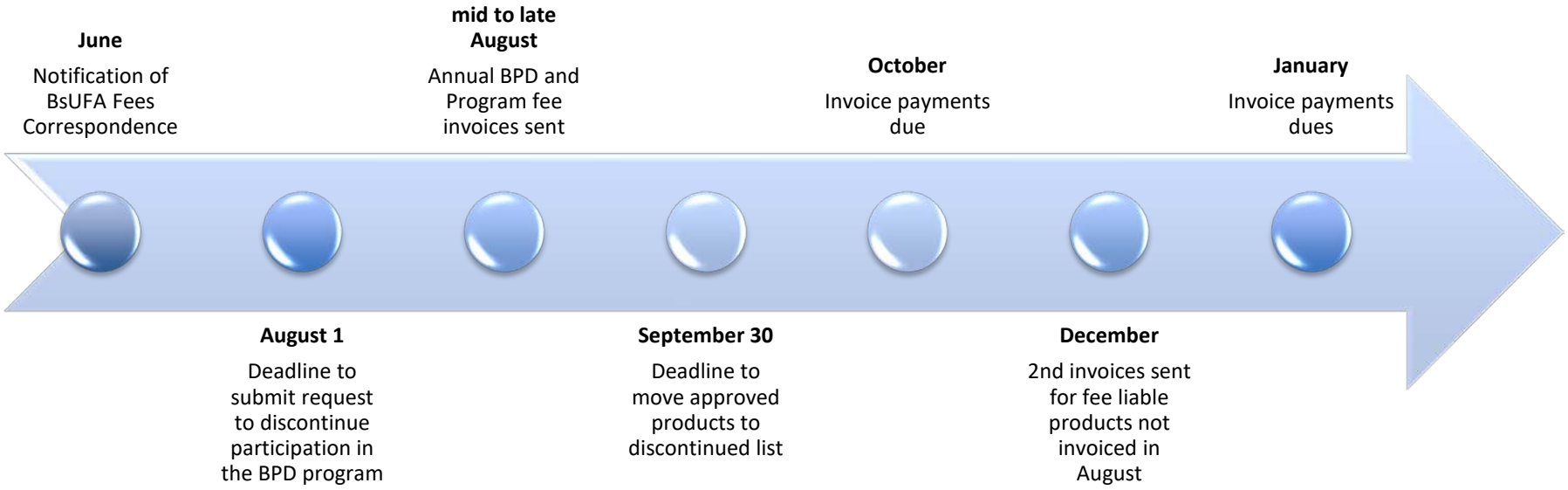
- ✓ Fee is due upon submission of the application
- ✓ BPD fees paid are not reduced from the application fee

PROGRAM FEE

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



INVOICE TIMELINE



THERAPEUTIC BIOSIMILAR BIOLOGICAL PRODUCTS LIST

- Contains all user fee-eligible and discontinued (not marketed) products
- The list is available on the BsUFA website[1]
- Companies are responsible for alerting the User Fee staff of any discrepancies

[1] https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM610868.pdf

FEE RATES FOR FY 2018 AND FY 2019

		FY 2018	FY 2019
BPD	Initial	$227,213	$185,409
	Annual	$227,213	$185,409
	Reactivation	$454,426	$370,818
Application	w/Clinical Data	$1,746,745	$1,746,745
	w/o Clinical Data	$873,373	$873,373
Program		$304,162	$304,162

Fiscal Year (FY): October 1 through September 30

ANNUAL SURVEY

- Sent to biosimilar sponsors in April of each year
- Requests information on sponsor's plans for the current and upcoming fiscal year with respect to:
  - BPD programs
  - Applications
  - Approved biosimilar biological products
- Assists the FDA in determining fees for the next fiscal year

SMALL BUSINESS WAIVER

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 biological product application and introduced or delivered for introduction into interstate commerce
- The applicant, including its affiliates, is submitting its first biosimilar biological product application

SMALL BUSINESS WAIVER

Recommend submitting Form FDA 3971 (Small Business Waiver and Refund Request) to the user fee staff at least 4 months prior to the submission of the application

https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM584476.pdf

REFUNDS

No refund for:

- initial BPD fee
- reactivation fee

Refund may be requested for:

- annual BPD fee
- application fee
- program fee

WAIVERS AND REFUNDS – 180 DAY RULE

- To qualify for consideration for a waiver or for a refund of any fee collected, a formal written request for such waiver or refund should be submitted not later than 180 days after such a fee is due

- Request can be submitted to the User Fee staff on Form FDA 3913 (User Fee Payment Refund Request)

https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492188.pdf

HELPFUL RESOURCES

Guidance Document

- Assessing User Fees Under the Biosimilar User Fee Amendments of 2017

BsUFA Website

- https://www.fda.gov/bsufa

Listserv

- Sign up at the website above for updates on biosimilar user fees

Contact BsUFA User Fee staff

- CDERCollections@fda.hhs.gov
- 301-796-7900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