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

www.fda.gov
### GDUFA FY19 FEES

#### Fee Type Sub-Category  | Amount
--- | ---
ANDA  | $178,799
DMF  | $55,013
**Large**  | **$1,862,167**
**Medium**  | **$744,867**
**Small**  | **$186,217**
Domestic API  | $44,226
Foreign API  | $59,226
Domestic FDF  | $211,305
Foreign FDF  | $226,305
Domestic CMO  | $70,435
Foreign CMO  | $85,435

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**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](https://edm.fda.gov)
UPCOMING TIMELINE

FY 2019

- FY19 Fee Due
  - Oct 1st
- Withdrawal Deadline
  - Apr 1st

YOU'RE HERE

- FY19 Fee Due
  - Oct 1st

FY 2020

- FY20 Fee Due
  - Oct 1st
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 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
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?

- FDF Facility is identified in an approved ANDA as of Oct 1st.
- Does the facility own the ANDA?
  - NO: Is the facility affiliated with the ANDA owner?
    - NO: CMO
    - YES: Not a CMO
  - YES: Not a CMO
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- A facility will stop incurring a facility fee when it is withdrawn from all generic drug submissions before the fee due date.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.
✓ 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

- GDUFAC user fees information and updates: [www.fda.gov/gdufa](http://www.fda.gov/gdufa)
  - GDUFAC 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](http://go.fda.gov/subscriptionmanagement)
Biological products, including biosimilars, are large and generally complex molecules.
FEE STRUCTURE

Biosimilar Biological Product Development (BPD) Program
- Initial BPD Fee
- Annual BPD Fee
- Reactivation Fee

Approval Phase
- Application Fee

Marketing Phase
- Program 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
• 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
• Discontinue participation in the BPD program for a biosimilar biological product under development
  o Formal written request must be submitted by **August 1** of the preceding fiscal year
  o “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
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

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
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
• 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

- **June**
  - Notification of BsUFA Fees Correspondence

- **mid to late August**
  - Annual BPD and Program fee invoices sent

- **August 1**
  - Deadline to submit request to discontinue participation in the BPD program

- **September 30**
  - Deadline to move approved products to discontinued list

- **October**
  - Invoice payments due

- **December**
  - 2nd invoices sent for fee liable products not invoiced in August

- **January**
  - Invoice payments due
Contains all user fee-eligible and discontinued (not marketed) products

The list is available on the BsUFA website

Companies are responsible for alerting the User Fee staff of any discrepancies

<table>
<thead>
<tr>
<th>Service</th>
<th>FY 2018</th>
<th>FY 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPD Initial</td>
<td>$227,213</td>
<td>$185,409</td>
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<tr>
<td>BPD Annual</td>
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<td>BPD Reactivation</td>
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<td>Application w/ Clinical Data</td>
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<td>Application w/o Clinical Data</td>
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<tr>
<td>Program</td>
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<td>$304,162</td>
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</tbody>
</table>

Fiscal Year (FY): October 1 through September 30
• 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
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
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
No refund for:
  - initial BPD fee
  - reactivation fee

Refund may be requested for:
  - annual BPD fee
  - application fee
  - program fee
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
Guidance Document

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

BsUFA Website

- [https://www.fda.gov/bsufa](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](mailto:CDERCollections@fda.hhs.gov)
- 301-796-7900