PDUFA User Fees - What? How? When?

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October 27, 2020

Learning Objectives

- Type of fees assessed under PDUFA
- Determining billable products
- Invoicing timeline
- Fees due date
- Penalties associated with unpaid fees

PDUFA Fee Types

- PDUFA VI authorized two types of fees

Fee Type	% of Target Revenue for FY
Application	20%
Program	80%

- Target revenue amount set annually prior to the start of the new fiscal year
  - E.g. FY 2021 target revenue = $1,107,199,000
  - FR Notice published in August

Application Fee

- Due upon submission of application
  - FY 2021 Full Fee ($2,875,842) - Application for which **clinical data** (other than bioavailability or bioequivalence studies) with respect to safety or efficacy are **required for approval**
  - FY 2021 Half Fee ($1,437,921) - Application for which **clinical data** with respect to safety or efficacy are **not required for approval**
- Exceptions/Waivers (orphan, small business, public health/barrier to innovation)

Program Fee

- Annual fee
- FY 2021 Program Fee = $336,432
- Applied to each **approved** prescription drug product in an NDA/BLA
- Based on list of products described in section 505(j)(7)(A) or on a list created and maintained by the Secretary of products approved under human drug applications under section 351 of the Public Health Service Act

Determining billable products

Published lists of marketed prescription drug products		
Application Type	**Center**	**Published List**
NDA	CDER	Orange Book
BLA	CDER	CDER Therapeutic Biologic Products List
BLA	CBER	CBER Billable Biologics List

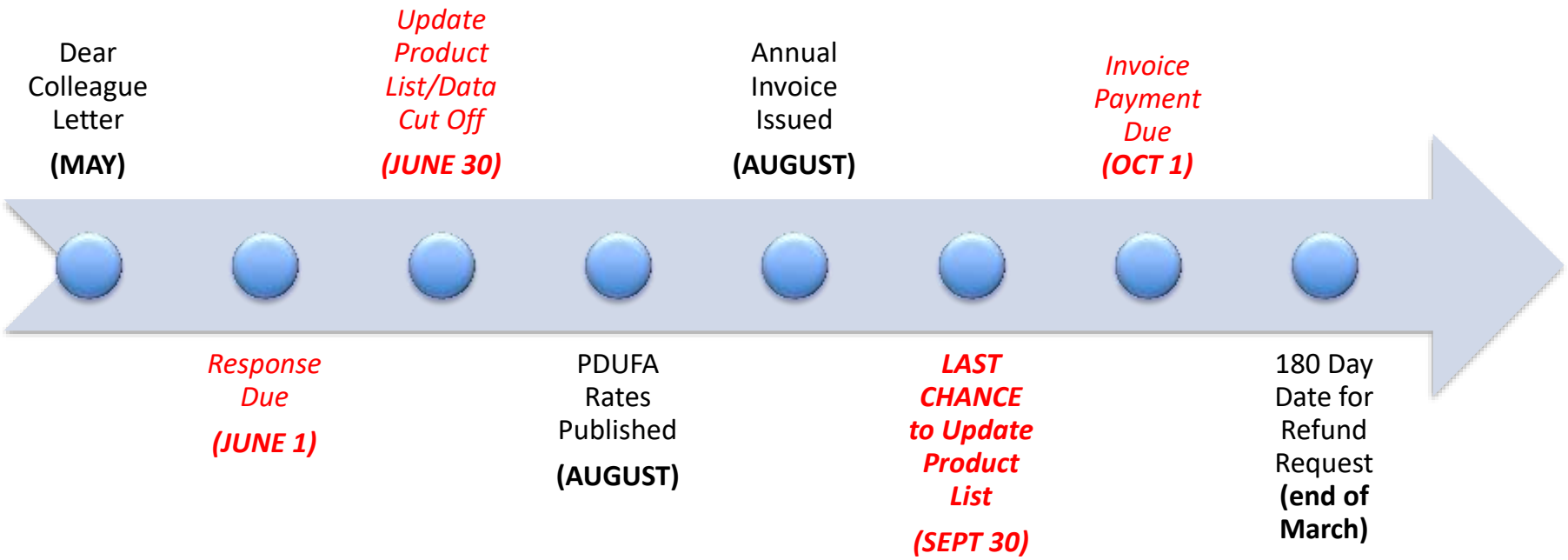
Exclusions, Limitations, Waivers

- Excluded from program fee
  - Discontinued/Withdrawn from Sale (no longer marketed)
  - Large Volume Parenteral (LVP)
  - Same Product as Another Product
- Limited to 5 products per application
- Waivers available (orphan, public health, barrier to innovation)
  - Submit request 3-4 months in advance (no later than 180 days after due date). See Waivers Guidance for more details.

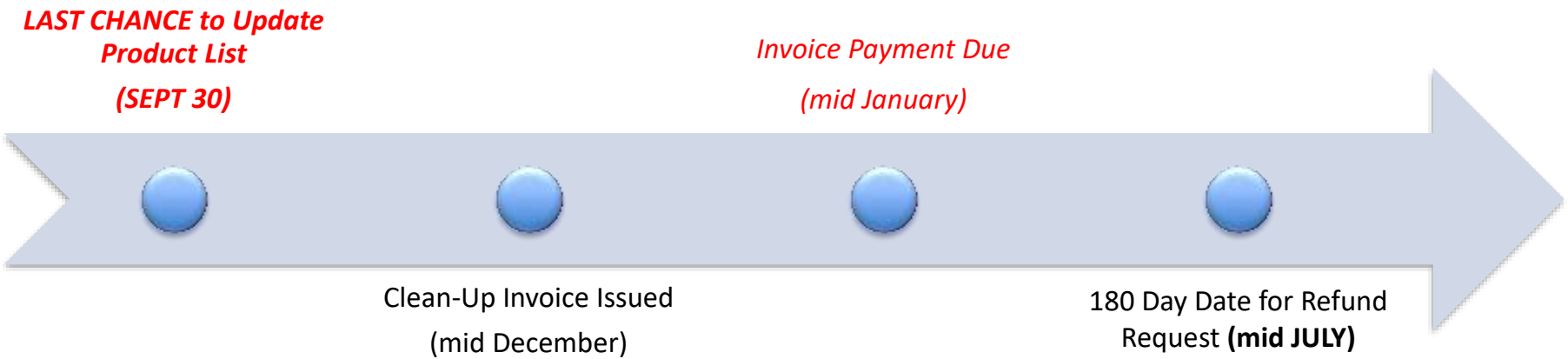
Invoicing Timeline

- Invoices for annual program fees are assessed to applicant holders with billable products once a year during one of the billing cycles
  - Annual Regular Billing Cycle: invoices are **issued in mid-August.** Fees are **due October 1st** of the fiscal year
  - Clean-Up Billing Cycle: invoices are **issued in mid-December.** Fees are **due in mid-January**

Annual Regular Billing Timeline



Clean-Up Billing Timeline



Examples of timing

Approval Date	Annual Program Fee Due
On or Before June 30, 2020 (e.g., June 1, 2020)	October 1, 2020 (Fiscal Year 2021- Annual Billing Cycle)
Between June 30, 2020 and October 1, 2020 (e.g., August 30, 2020)	Mid January 2021 (Fiscal Year 2021-Clean Up Cycle)
After October 1, 2020 (e.g., November 1, 2020)	October 1, 2021 (Fiscal Year 2022-*Pass Until Next Fiscal Year)*

Changes to published lists during billing

- Requests for changes in marketing status
  - Discontinuations, reactivations
- Transfer of ownership/name changes
- Submit no later than June 30th.
  - NDAs – Submit to NDA (cc: CDERCollections@fda.hhs.gov)
  - CBER BLAs –CBERPDUFAStaff@fda.hhs.gov (cc: CDERCollections@fda.hhs.gov)
  - CDER BLAs – CDERCollections@fda.hhs.gov

Attachment B

Please return this form along with the updated lists of products in Attachment B to CDERCollections@fda.hhs.gov.

For instructions on how to complete Attachment B, please refer to the attached Dear Colleague letter.

Product Checklist		
1.	☐	Reviewed all products in Attachment B and compared it to the three publicly available lists, i.e. Prescription Drug Product List, CDER Billable Biologic Product List & CBER Billable Biologic Product List
2.	☐	Added/Deleted products, as appropriate • Notified appropriate Agency point of contact per section III and IV of DCL letter
3.	☐	Contacted Orange Book Staff to discontinue CDER prescription products as needed
4.	☐	Contacted CDER User Fee Staff to discontinue CDER biologic products as needed
5.	☐	Contacted CBER User Fee Staff to discontinue CBER biologics products as needed

Penalties associated with unpaid fees

- Failure to pay application fee
  - Submission considered incomplete and not accepted for filing
- Arrears for non payment of annual fees
  - All incoming submissions considered incomplete and not accepted for filing (for the applicant and/or its affiliates)
- Other penalties:
  - Financial penalties incurred
  - Referral to debt collection agencies

Challenge Question 1

What published list determines billable CDER NDA products?

a) CDER BLA billable biologics list

b) CBER BLA Billable biologics list

c) Orange Book

Challenge Question 2

If a billable product is approved in June 2020, when can the firm expect their bill for the FY 2021 fee to be due?

a) October 2020

b) January 2020

c) October 2021

Important Dates

- March 30, 2021 – 180 day date (LAST CHANCE) to submit waiver/refund request for FY 2021 annual program fees
- June 2021 – If you qualify, submit waiver request for program fees for upcoming fiscal year (FY 2022) billing
- June 30, 2021 (*at the latest*) – Notify FDA to update product list (Orange Book, CDER/CBER BLA List) for FY 2022 billing
- Sept. 30, 2021 – LAST CHANCE to update product list for FY 2022 billing
- Oct. 1, 2021 – FY 2022 Annual Program Fee Due

Resources

- PDUFA Website
- Orange Book
- CDER Therapeutic Biologic Products List
- CBER Billable Biologics List
- Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format August 2020
- Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products Oct 2019

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Questions?

Center for Drug Evaluation and Research

Office of Management

Division of User Fee Management and Budget Formulation

CDERCollections@fda.hhs.gov

301-796-7900


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