

Drug Master Files from a GDUFA II User Fee Perspective

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**SBIA-DMF and Drug Substance Workshop
March 3 & 4, 2021**

Outline



- Important GDUFA II User Fee Timeline
- User Fee System and Payment Information
- User Fee Assessments for DMFs and Facilities
- Issues that potentially affect DMF reviews and/or ANDA approvals

GDUFA TIMELINE

**Early
August**

- ✓ Federal Register Notice posting

**Early
September**

- ✓ The User Fee System (iStore) open for early annual payments

**October
1st**

- ✓ Fiscal Year (FY) starts
- ✓ Annual payments due date

**October
21st**

- ✓ Facility's grace period ends

Important Timeline for FY 2022



- FY Cross-Over Period (Sept – Nov): Two FYs cover sheets available in the FDA User Fee System
 - DMF Fees: Both FY21 & 22 cover sheets are available
 - Facility Fees: Both FY21 & 22 cover sheets are available from Sept to Oct 1; FY21 cover sheet is no longer available after Sept 30, 2021
- Facility fees
 - Early payments are encouraged
 - Arrears List Posting starts to include outstanding FY22 fees after the grace period
- Recommended actions
 - Facility must be withdrawn from all approved generic drug submissions prior to Oct 1st stop incurring the facility fee for the applicable FY
 - During Cross-Over period, selection of the correct FY coversheet is important

- GDUFA cover sheet is required for each payment
- Cover Sheet Creation is available via FDA User Fee System
 - Review cover sheets for accuracy before submitting payments
- Payment options: pay.gov, check, and wire transfer
 - Cover sheet PIN must be referenced on each payment
 - Be mindful of wire transfer fees
- Submissions of facility cover sheet copies are not required

- Requests within the 180 calendar days from the payment receipt date
 - Refund & Transfer request forms
 - Tax ID or DUNS Number
 - Copies of cover sheets (for transfer requests)
- Payment Transfers not allowed for closed FYs
- DMF payments not be refundable



- 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

DMF FEE ASSESSMENTS



- DMF fees: Type II API DMF referenced on or after October 1, 2012, in a generic drug submission
- FY fee rate is determined by the Payment Receipt Date
- Due on the earlier of:
 - First referenced generic drug submission
 - DMF holder requests the initial completeness assessment (Payment Receipt date)



- **No fees** are required if:
 - Only referenced in PET applications
 - State/federal entities of non-commercial products

GDUFA defines an FDF as:

- (A) a drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application;
- (B) a drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or
- (C) any combination of an active pharmaceutical ingredient (as defined in the statute) with another component of a drug product for purposes of production of a drug product described in subparagraph (A) or (B).

GDUFA defines an API as:

- (A) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended—
 - (i) to be used as a component of a drug; and
 - (ii) to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or
- (B) a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become a substance or mixture described in subparagraph (A).

- API Mixtures:
 - FDF DMFs:
 - No DMF fees required; however, the referenced API DMFs are subject to DMF fees
 - In-process mixture facilities are subject to FDF (or CMO) facility fees while “hidden” API facilities are subject to API fees
 - API-Excipient Mixtures for stability purposes:
 - DMFs are subject to DMF fees
 - Facilities are subject to API facility fees
- Atypical DMFs:
 - Subject to both DMF & API Facility fees if referenced as APIs
- Starting Materials vs Crude APIs vs API intermediates



- ✓ GDUFA user fees information and updates:
www.fda.gov/gdufa
- ✓ General user fee-related questions:
CDERCollections@fda.hhs.gov
- ✓ GDUFA User Fee Lists:
<https://www.fda.gov/industry/generic-drug-user-fee-amendments/user-fee-lists>
- ✓ GDUFA Guidance and MAPPs:
<https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-guidances-and-mapps>
- ✓ FDA User Fee System:
https://userfees.fda.gov/OA_HTML/gdufaCAcdLogin.jsp

THANK YOU!



- For questions regarding the content of this presentation, please type them into the 'Q&A Box' in the bottom right hand corner of your screen so that we can address them during the scheduled Q&A panel after this session.
- If you have any questions on this presentation after the workshop is over, please send them to the email DMFWorkshop2021@fda.hhs.gov by March 19, 2021 for inclusion in the follow-on webinar on April 9, 2021.

