AMCP | Regulatory NewsBREAK

FDA Issues User Fee Rates for FY2024

- The Food and Drug Administration (FDA) issued several notices announcing the Fiscal Year 2024 user fee rates.
- These fees apply to the period from October 1, 2023, through September 30, 2024.

Prescription Drug User Fee Rates

- FDA assesses prescription drug user fees as follows: (1) application fees are assessed on certain types of applications for the review of human drug and biological products and (2) prescription drug program fees are assessed on certain approved products.
- For FY 2024, the rates are as follows:

Fee Category	Fee Rates for FY 2024
Application	
Requiring clinical data	$4,048,695
Not requiring clinical data	$2,024,348
Program	$416,734

Generic User Fee Rates

- FDA is authorized to collect to assess and collect fees for abbreviated new drug applications (ANDAs); drug master files (DMFs); generic drug active pharmaceutical ingredient (API) facilities, finished dosage form (FDF) facilities, and contract manufacturing organization (CMO) facilities; and generic drug applicant program user fees.
- For FY 2024, the rates are as follows:

Table 1.--Fee Schedule for FY 2024

Generic Drug Fee Category	Fees Rates for FY 2024
Applications	
Abbreviated New Drug Application (ANDA)	$252,453
Drug Master File (DMF)	$94,682
Facilities	
Active Pharmaceutical Ingredient (API)--Domestic	$40,464
API--Foreign	$55,464
Finished Dosage Form (FDF)--Domestic	$220,427
FDF--Foreign	$235,427
Contract Manufacturing Organization (CMO)--Domestic	$52,902
CMO--Foreign	$67,902
GDUFA Program	
Large size operation generic drug applicant	$1,729,629
Medium size operation generic drug applicant	$691,852
Small business generic drug applicant	$172,963

Biosimilar User Fee Rates

- The initial biosimilar biological product development (BPD) fee for a product is due when the sponsor submits an investigational new drug (IND) application for a biosimilar biological product application or within 7 calendar days after FDA grants the first BPD meeting, whichever occurs first. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits an accepted marketing application, the sponsor discontinues participation in FDA's BPD program, or the sponsor has been administratively removed from the BPD program.
- For FY 2024, the rates are as follows:

Fee Category	Fee Rates for FY 2024
Initial BPD	$10,000
Annual BPD	$10,000
Reactivation	$20,000
Applications	
Requiring clinical data	$1,018,753
Not requiring clinical data	$509,377
Program	$177,397

Outsourcing Facility Fee Rates

- FDA collects establishment and reinspection fees related to entities that compound human drugs and elect to register as outsourcing facilities.
- For FY 2024, the rates are as follows:

Qualified Small Business Establishment Fee	$	6,196.00
Non-Small Business Establishment Fee	$	20,036.00
Reinspection Fee	$	18,588.00

More on This Topic:

- Prescription Drug User Fee Rate Notice
- Generic User Fee Rate Notice
- Biosimilar User Fee Rate Notice
- Outsourcing Facility Fee Rate Notice

For questions, please reach out to Tyler Thorne.