

# 30 Years of PDUFA

## 1992 - 2022



The Prescription Drug User Fee Act (PDUFA) was established by Congress in 1992 to help the FDA meet public health commitments and expedite the drug review and approval process. It must be reauthorized every five years and was renewed in 1997, 2002, 2007, 2012, 2017, and 2022.



### PDUFA User Fee

User fees are applicable to certain human drug applications submitted under 505(b) of the Federal FD&C Act or certain biologic products under 351(a) of the PHS Act.



### Exceptions to PDUFA

- Certain Previously Filed Applications
- Designated Orphan Drug or Indication
- Skin-Test Diagnostic Products

## Benefits of PDUFA



- Fosters innovation
- Ensures adequate staffing with qualified personnel
- Enables a more consistent and predictable process
- Shorter review timelines get safe effective medicines to patients faster



### PDUFA Date

A deadline for the FDA to review new drug & biologic applications. The clock starts on the day the application is accepted by the agency. It allows 10 months for new drug/biologic applications and 6 months for priority reviews.



### PDUFA VII

On September 30, 2022, the President signed the FDA User Fee Reauthorization Act of 2022 into law. The Act includes the reauthorization of the Prescription Drug User Fee Act (PDUFA VII) & spans fiscal years 2023-2027.

## PDUFA VII FEES

Application - Clinical Data Required

**2022**

\$3,117,218

**2023**

\$3,242,026

Application - No Clinical Data Required

\$1,558,609

\$1,621,013

Program Fee

\$369,413

\$393,933

Program fees are assessed annually for each eligible prescription drug product that is identified in a human drug application approved as of October 1 of the fiscal year.



## QUESTIONS



For any questions regarding PDUFA Fee requirements, waivers, reductions or refunds, please send an email to [CDERCollections@fda.hhs.gov](mailto:CDERCollections@fda.hhs.gov).  
Contact the User Fee Helpdesk at [userfees@fda.gov](mailto:userfees@fda.gov) to make or confirm the status of a payment.