

1. WHAT IS PDUFA?

The Prescription Drug User Fee Act (PDUFA) is a law that allows FDA to collect fees from biopharmaceutical companies to support the review of new medicines. These fees fund staff, technology, and processes that make reviews more predictable and timely, and they augment non-user fee appropriations provided by Congress. These fees support the review process under established regulatory standards.

2. WHY DOES PDUFA MATTER TO PATIENTS?

PDUFA directly affects how quickly and efficiently FDA can review new therapies, resulting in more timely access to treatments. Since it was enacted in 1992, the average review time for new medicines has decreased from over two years to less than a year. PDUFA also funds programs that improve patient engagement, benefit-risk assessment, and communication.

3. HOW OFTEN IS PDUFA RENEWED?

PDUFA is reauthorized every five years. Each cycle includes negotiations between FDA and industry, followed by Congressional review and approval.

4. WHAT IS INCLUDED IN A PDUFA REAUTHORIZATION?

Each cycle includes:

- Commitments to improve review processes
- Investments in scientific capacity
- Enhancements to patient engagement
- Performance goals for FDA review timelines

5. DO PATIENT GROUPS HAVE A ROLE IN PDUFA NEGOTIATIONS?

Yes — while formal negotiations occur between FDA and industry, patient groups participate through public stakeholder consultation meetings throughout the negotiation process, docket comments, and Congressional engagement.

6. DOES PDUFA SPEED UP DRUG APPROVALS?

PDUFA does not change FDA's standards for safety or effectiveness. It provides resources that allow FDA to complete reviews more efficiently and predictably.

7. HOW DOES PDUFA AFFECT RARE DISEASE DRUG DEVELOPMENT?

PDUFA supports:

- Specialized review staff
- Scientific expertise in rare diseases
- Early engagement programs for sponsors
- Tools for evaluating small population trials

8. WHAT ARE PDUFA "GOALS"?

These are performance targets FDA commits to meeting, such as:

- Review timelines
- Meeting scheduling
- Communication milestones

They help ensure transparency and accountability. Each time PDUFA is reauthorized, there is a new PDUFA Commitment Letter published that describes the goals, which reflect the priorities of FDA and the regulated industry have identified.

9. WHAT TYPES OF FEES DOES PDUFA AUTHORIZE?

PDUFA includes:

- **Application fees** – Fees due when a sponsor submits an application for approval of a new medicine
- **Program fees** – Annual fees paid for most approved medicines

There are also numerous waivers and exemptions designed to prevent fees from being an impediment to public health and innovation.

10. HOW DOES PDUFA SUPPORT SCIENTIFIC INNOVATION?

PDUFA funds FDA programs to ensure the regulator has the expertise, experience, and infrastructure required to apply cutting-edge regulatory science in its decision-making. Some specific examples include Model-Informed Drug Development, Real World Evidence, and the use of Digital Health Technologies. These help FDA evaluate cutting edge therapies developed through the use of these innovative methods.

11. WHAT HAPPENS IF PDUFA IS NOT REAUTHORIZED ON TIME?

FDA would lose a major portion of its drug review funding, leading to hiring freezes and furloughs, making it harder for FDA to recruit and retain the expertise it needs and review delays, which could reduce patient access to innovative therapies.

This is why reauthorization is typically bipartisan and high priority for Congress.

12. HAS PDUFA BEEN SUCCESSFUL?

Yes, the average review time for new applications has dropped from 29+ months before PDUFA's enactment to less than 12 months today. Products are routinely approved in the U.S. first before being approved in other global regions.