

The Prescription Drug User Fee Act (PDUFA)

Driving Patient Access, Innovation, and U.S. Leadership



For more than 30 years, the Prescription Drug User Fee Act (PDUFA) has helped ensure patients receive more timely access to safe and effective medicines while strengthening America's leadership in biopharmaceutical innovation.

By providing FDA with additional resources to review new medicines and establishing clear performance goals, PDUFA has reduced review times, increased regulatory predictability, and helped make the United States the first-launch market for most innovative therapies.

A RESPONSE TO PATIENT NEED

Before PDUFA...

- FDA review times often exceeded **2 years**
- U.S. patients frequently waited longer than patients overseas for new therapies
- 60% of new medicines reached foreign markets more than a year before U.S. approval



How PDUFA Works

Congress enacted PDUFA in 1992 as a bipartisan solution to strengthen FDA's new review capacity.

UNDER PDUFA:

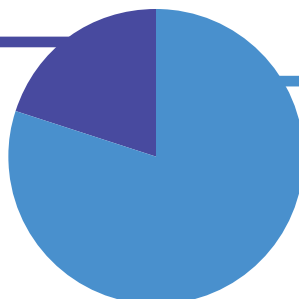
- Biopharmaceutical companies pay user fees that supplement FDA resources
- FDA commits to specific performance goals related to review timelines in which FDA evaluates efficacy and safety. FDA's rigorous standards for evaluating efficacy and safety remain unchanged.
- FDA, industry, Congress, and patient advocates contribute to each reauthorization cycle

FUNDING STRUCTURE

Application Fee

Fee due when a sponsor submits a New Drug Application (NDA) or Biologics License Application (BLA)

20% of the total prescription drug user fee revenue comes from application fees



Program Fee

Annual fee for most approved prescription drug products without an approved generic

80% of the total prescription drug user fee revenue comes from program fees

Having the majority of PDUFA user fees revenue come from program fees is intended to support a stable funding source for FDA activities.

Resourcing FDA

The PDUFA program provides additional resources to FDA for the review of new drugs, while also providing sponsors with greater predictability and enhanced engagement with the Agency during drug development. The PDUFA provisions are limited to improving FDA performance in certain areas or allocating resources to new regulatory review areas and functions.

- The agreement cannot be used to change regulatory policy or alter FDA statutory requirements
- In exchange for paying user fees, Industry receives from FDA a commitment to meet certain performance goals
- Prior to each 5-year reauthorization cycle, FDA and industry negotiate the performance goals, which are finalized in a written agreement

PDUFA is reauthorized by Congress every **5 years**, providing the biopharmaceutical industry and FDA with the opportunity to make changes or add new provisions that will further improve the program.

PDUFA VII expires September 30, 2027. If PDUFA is not reauthorized by July 2027, FDA will begin a process to send layoff notices to FDA employees.

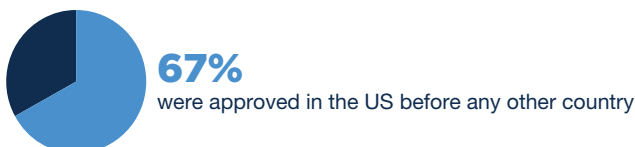
Results for Patients

Before PDUFA, it often took FDA more than 2 years to review new medicines. The median review time for a new medicine is now just 10 months for standard applications and 8 months for priority applications.

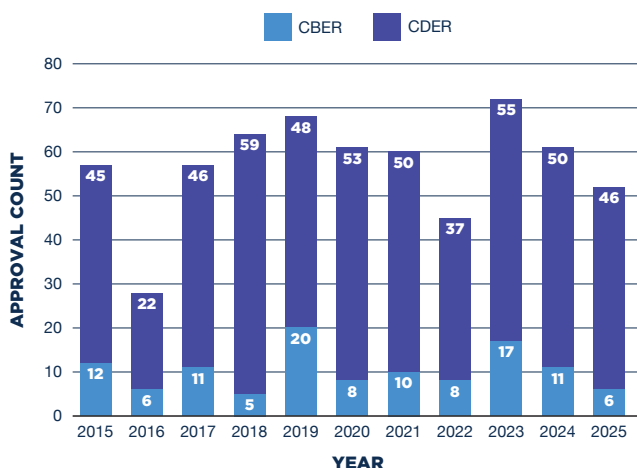
In 2025, the Center for Drug Evaluation and Research (CDER) approved 46 novel drugs:



In 2025, the Center for Biologics Evaluation and Research (CBER) approved 6 novel biologic license applications (BLAs):



CDER AND CBER NOVEL AGENT APPROVALS (2015-2025)



Note: CBER approval numbers do not include reagents, cord blood, or immunoassays.

Source: [FDA, Novel Drug Approvals 2025](#) & [FDA 2025 Biological License Application Approvals](#)

Why PDUFA Matters

FOR PATIENTS

- Efficient regulatory review process
- Faster access to innovative medicines and biologics
- More predictable review timelines
- Timely availability of treatments for serious and rare diseases

FOR INNOVATION

- Supports an efficient and predictable regulatory environment
- Encourages investment in research and development
- Facilitates collaboration between FDA, industry, and patients

FOR U.S. LEADERSHIP

- Nearly **70% of new medicines in 2025** were approved first in the U.S.
- More than **1,700 novel drugs and biologics** approved since PDUFA's enactment
- Helps maintain America's position as the global leader in biopharmaceutical innovation

Continued reauthorization of PDUFA is essential to maintaining FDA review capacity, supporting patient access to innovative medicines, and preserving U.S. leadership in biomedical innovation.

**WE
WORK
FOR
HEALTH**