

The Prescription Drug User Fee Act (PDUFA VIII)

Overview

The Prescription Drug User Fee Act (PDUFA) provides the U.S. Food and Drug Administration (FDA or Agency) with critical resources to fulfill its mission of protecting and advancing public health. With PDUFA, the FDA is funded through user fees collected from biopharmaceutical companies that help it keep pace with the growing number and complexity of innovative drugs and biologics under review. This funding supplements Congressional appropriations.

Thanks in large part to PDUFA, the United States now leads the world in the introduction of new medicines, and the FDA's human drug review program is the global gold standard for regulatory review and approval.

Since its enactment in 1992, PDUFA has:

- Provided patients with faster access to **over 1,700 new drugs and biologics**, including treatments for cancer, rare diseases, cardiovascular conditions, neurological disorders and infectious diseases.
- Strengthened the FDA's ability to efficiently review applications, incorporate scientific advances into regulatory decision-making and help **ensure patients benefit from the latest medical innovations**.
- Provided greater regulatory predictability, supporting continued investment in biopharmaceutical research and development, and **strengthening America's competitive edge in innovation**.

During each five-year reauthorization cycle, the FDA and the biopharmaceutical industry, with input from patient groups and other stakeholders, identify initiatives and negotiate commitments that modernize the review process, enhance accountability and transparency and support the development of the next generation of treatments.

To help make the review process more efficient and predictable, biopharmaceutical companies currently pay two different user fees under PDUFA.

- **Application fee:** Fee due when a sponsor submits a New Drug Application (NDA) or Biologics License Application (BLA).
- **Program fee:** Annual fee for most approved prescription drug products without an approved generic.

The latest reauthorization of PDUFA (PDUFA VII) was signed into law on September 30, 2022, and expires September 30, 2027.

The Impact of PDUFA

BEFORE PDUFA

Late 1980s

29
MONTHS

Average time for FDA to complete an application review

70%
OUTSIDE

of new medicines were first approved outside the U.S.

AFTER PDUFA

Today

10 MONTHS STANDARD
6 MONTHS PRIORITY

Current PDUFA review goal timelines for new medicine applications

~70%
U.S. FIRST

of new medicines are now approved in the U.S. before any other country

A Closer Look at PDUFA VIII: Strengthening America's Competitive Edge in Biopharmaceutical Innovation

The PDUFA VIII commitments will modernize the regulatory review of innovative medicines, advance domestic manufacturing and strengthen America's regulatory ecosystem to keep pace with scientific advances and efficiently review new medicines.

Reduce delays in the drug regulatory review process

- Introduce new mechanisms for timely feedback during drug review through enhanced FDA-company interactions, helping identify and resolve issues before they cause delays.
- Establish a program to address manufacturing and facility issues earlier, reducing the risk of late-stage setbacks.
- Further enhance efficiency by ensuring predictable reviews of pivotal clinical trial protocols and streamlining the review of products with multiple indications.

Help enable the FDA to keep pace with scientific innovation

- Makes successful pilot programs, including real-world evidence, innovative trial designs and patient-focused drug development, a standard part of FDA review.
- Advance rare disease drug development, including for pediatric patients, through a mechanism for collaboration on the development of novel efficacy endpoints.
- Enhance FDA surveillance and capabilities, including through improving existing FDA tools for monitoring post-marketing safety data, with the aim of reducing the need for additional studies after approval.

Strengthen public trust by improving transparency and accountability around how user fees are spent and how the program performs

- Evaluate FDA performance against agreed-upon goals and identify actionable recommendations for improvement through an independent, third-party analysis.
- Dedicate user fee funding to support FDA's restaffing of drug review personnel.
- Evaluate the new manufacturing facilities program through a third-party assessment to ensure its effective in timely addressing any manufacturing facility issues.