What is PDUFA?

Congress enacted the Prescription Drug User Fee Act (PDUFA) in 1992 to provide the U.S. Food and Drug Administration (FDA) with critical resources to fulfill its central mission – protecting and advancing the public health.

Thanks in large part to PDUFA, the U.S. leads the world in the introduction of new medicines, providing patients with faster access to needed treatments, and the FDA's human drug review program is the global gold standard for regulatory review and approval.

PDUFA has been reauthorized six times since 1992 and has consistently earned strong bipartisan support. The latest reauthorization of PDUFA (PDUFA VII) was signed into law on September 30, 2022, and expires on September 30, 2027.

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.



Before

Before PDUFA, it often took FDA more than **two years** to review new medicines.

Now

Now the median approval time for a new medicine is just **10 months** for standard and **6 months** for priority review.

Learn more at PhRMA.org/PDUFA

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What is PDUFA VIII?

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

PDUFA VIII will strengthen America's competitive edge by:

Reducing delays in the drug regulatory review process

- Introducing new mechanisms for timely feedback during drug development and review through enhanced FDA-company interactions, helping identify and resolve issues before they cause delays.
- Establishing a program intended to address manufacturing and facility issues earlier, reducing the risk of late-stage setbacks.
- Further enhancing efficiency by providing predictable timelines for review of pivotal clinical trial protocols.

Helping enable the FDA to keep pace with scientific innovation

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

Strengthening public trust by improving transparency and accountability

- Evaluating FDA performance against agreed-upon goals and identifying actionable recommendations for improvement through an independent, third-party assessment.
- Providing dedicated user fee funding to support FDA's restaffing of drug review personnel.
- Assessing the new manufacturing facilities program through an independent, third-party assessment to ensure it is effective in timely addressing any manufacturing facility issues.

The promise of breakthroughs in biopharma innovation depends on a modern regulatory framework to help ensure patients have timely access to lifesaving medicines. **PDUFA VIII will help fulfill this promise by helping the FDA keep pace with scientific advancements while strengthening the American regulatory ecosystem.**

Learn more at PhRMA.org/PDUFA

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