WHAT IS PDUFA?

The Prescription Drug User Fee Act (PDUFA) was first enacted in 1992 as a bipartisan solution to increase the efficiency of prescription drug review at the U.S. Food and Drug Administration (FDA). PDUFA has helped the FDA fulfill its central mission – to help protect and advance public health – by allowing the agency to keep pace with the number and complexity of innovative drugs and biologics entering the review pipeline. In large part because of 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.

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

PDUFA has been reauthorized five times since 1992 and has consistently enjoyed strong bipartisan support. The current PDUFA VI program ends September 30, 2022, and must be reauthorized by Congress before it expires to ensure continued FDA review activities.

To help make the review process more efficient and predictable, biopharmaceutical companies 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.

WHAT IS PDUFA?

PDUFA is reauthorized every five years, providing the biopharmaceutical industry and FDA with the opportunity to make changes or add new provisions that will further improve the program. The PDUFA VII agreement will strengthen review fundamentals at FDA and address new areas, while enhancing accountability and transparency. **Specifically, PDUFA VII will:**

- Strengthen scientific dialogue and advance innovation through expanding opportunities for obtaining FDA regulatory feedback and clarity throughout the drug development process.
- Enhance patient-centric drug review, such as the incorporation of patient-centric data into drug development and regulatory reviews and supporting safety monitoring.
- Support the next wave of advanced biological therapies, such as cell and gene therapies, and facilitate broader use of novel trial designs and approaches for rare and ultra-rare diseases.
- Modernize regulatory evidence generation and drug development tools, such as advancing the use of real-world evidence for regulatory decision-making.
- Advance digital technologies and information technology (IT) infrastructure and modernize FDA's data and IT capacity and capabilities, including adoption of cloud-based technologies.
- Enhance innovation in manufacturing and product quality reviews, including incorporating best practices from COVID-19 lessons learned.
- Build on PDUFA VI efforts to modernize FDA financial and staff resource management.

New developments in medical and fundamental science – including immunotherapies and cell and gene therapies – hold the promise of treating debilitating diseases such as cancer, diabetes and many rare disorders. Fulfilling this promise depends on a modern regulatory framework supported by PDUFA that helps ensure patients have timely access to lifesaving medicines.