

PDUFA At-a-Glance



What is PDUFA?

The Prescription Drug User Fee Act ([PDUFA](#)) is a bipartisan law enacted in 1992 that authorizes the FDA to collect user fees from biopharmaceutical companies to support the review of new medicines. These fees strengthen the overall review system but do not influence or guarantee approval of any specific drug. Congress must pass the reauthorization of PDUFA in 2027, as it does every five years.



Why Did Congress Create PDUFA?

Before PDUFA, the FDA faced resource constraints that resulted in slow and unpredictable review timelines. U.S. patients often waited longer than those in other countries to access new treatments. Congress established PDUFA to provide a dedicated, sustainable funding stream, enabling the FDA to hire scientific staff, modernize its processes, and review therapies more efficiently — without compromising its rigorous standards for safety and effectiveness.



How Does PDUFA Work?

Biopharmaceutical companies pay application fees when submitting new drug applications, as well as ongoing program fees for approved products. These funds are pooled to support the FDA's drug review activities, including staffing, scientific expertise, and safety monitoring. In exchange, the FDA commits to defined review timelines, regular engagement with developers, and measurable performance benchmarks that promote transparency and accountability. This framework aligns expectations between regulators and developers throughout the review process.



How is the PDUFA Agreement Reached?

Every five years, the FDA and the biopharmaceutical industry negotiate a set of priorities and performance goals designed to strengthen the drug review process. These discussions focus on improving the efficiency, predictability, and scientific capabilities of the FDA while supporting continued medical innovation. The negotiations culminate in a commitment letter that, following administration clearance, is transmitted to Congress for codification as part of the PDUFA reauthorization process.



How Does PDUFA Advance Patient Access and Innovation?

PDUFA has played a critical role in accelerating patient access to new therapies while maintaining the FDA's high standards for safety and effectiveness. By providing the resources needed for timely reviews, it helps bring innovative treatments — often developed by biotechs targeting unmet medical needs — to patients sooner. PDUFA also supports a stable regulatory environment that encourages continued scientific advancement and investment in new therapies.



Why Does PDUFA Matter Today?

User fees help sustain a timely, effective process. This is critical for biotech firms, which operate with limited resources and rely on predictable regulatory timelines to advance innovative therapies. A strong PDUFA framework supports the entire ecosystem and allows the U.S. to maintain global biotech leadership by reducing uncertainty, enabling R&D investments, and moving promising treatments through the pipeline efficiently.