GENERICS | ACCESS | PROJECT

Generic Drug User Fee Amendments (GDUFA) IV:

Increasing Patient Access to Affordable Drugs

Patients, and the U.S. health care system, have benefited significantly from increased access to generic drugs. Generics account for 90% of U.S. prescription volume but only 12% of total prescription drug spending. As a result, more patients can access lower-cost medicines, saving them money and driving substantial savings across the health care system. Over the past decade from 2014 to 2024, generic drugs generated an estimated $3.4 trillion in savings, including $467 billion in 2024 alone.[1]

What is GDUFA?

The Generic Drug User Fee Amendments (GDUFA) were first enacted by Congress in 2012 to ensure FDA has resources to review generic drug applications, strengthening competition with brand-name drugs and reducing costs for consumers. The program established a user fee structure through which the generic drug industry pays a fee for each drug application, helping fund FDA regulatory activities, including efforts to reduce the backlog of generic drug applications that existed before GDUFA.

Planning is underway for GDUFA IV, which will cover fiscal years 2028 through 2032. FDA has begun the formal reauthorization process, including a kickoff meeting held in July and monthly discussions with industry and stakeholders to shape program goals and proposed updates.[2]

What does this mean for patients?

As FDA prepares its GDUFA IV commitment letter, the agency has outlined priorities and potential program updates expected to deliver direct patient benefits. These efforts aim to strengthen the quality, reliability and availability of generic medicines, supporting more consistent access to affordable treatments, particularly serious and chronic conditions.

Patient-focused areas under discussion include:

- Enhancing supply chain reliability through domestic manufacturing incentives and new pilot programs.
- Improving product quality and consistency by advancing FDA's proposed PreCheck program.
- Supporting more predictable and timely generic drug reviews through user fee structures and enhanced program performance.[3]

What's next?

As FDA's Office of Generic Drugs works to develop the GDUFA IV program, the Generics Access Project (GAP) will help raise awareness of measures that prioritize patient needs, including:

- Centering unmet patient needs in policies affecting access to generic medicines.
- Emphasizing the review and approval of first- and second-generation complex generics.
- Establishing a consistent and formal process for incorporating patient perspectives into the review and approval of generic drugs.

GAP will continue to champion patient priorities throughout the GDUFA IV process, including the need for transparent quality standards, clear communication and meaningful patient involvement in policies that influence generic drug availability and affordability.

Join the Generics Access Project to participate in these discussions with FDA and help advance patient access to safe, effective and affordable medicines.

1. Association for Accessible Medicines. (2025). *2025 U.S. generic & biosimilar medicines savings report.* https://accessiblemeds.org/resources/reports/2025-savings-report/.
2. U.S. Food and Drug Administration. (2026). *GDUFA IV: Fiscal years 2028–2032.* U.S. Department of Health and Human Services. https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iv-fiscal-years-2028-2032.
3. U.S. Food and Drug Administration. (2025, July 11). *Public meeting on the reauthorization of the Generic Drug User Fee Amendments (GDUFA)* [Transcript]. https://www.fda.gov/media/187902/download.