GDUFA IV
Advocate Engagement Toolkit

GENERICS | ACCESS | PROJECT

FALL 2026

Table of Contents

Background

The Generic Drug User Fee Amendments, or 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.

GDUFA frameworks have successfully allowed more patients to have access to lower-cost drugs, saving them money, and driving down overall healthcare costs.

GDUFA I (2012-17) expedited the review and approval process and established equivalent requirements between domestic and foreign manufactures of generic drugs to ensure safe and prompt access to these human generic drugs.

GDUFA II (2018-22) used that experience to reduce the number of review cycles to increase the number of generic drugs approved while preserving the highest safety standards.

GDUFA III (2022-27) built on earlier agreements by improving review efficiency, strengthening communication between FDA and applicants and supporting timely review of generic drug applications.

The Generics Access Project supports the enactment of GDUFA IV to maintain and increase patient access to affordable drugs.

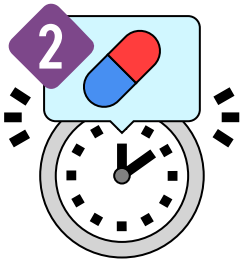
Key Messages

The Generics Access Project supports the reauthorization of GDUFA IV because it will help FDA ensure patients continue to have timely access to safe, effective and affordable generic medicines. Organizations are encouraged to tailor these messages with examples from their own disease area and patient community.

GDUFA IV will help increase access to affordable medicines.

Generic medicines account for 90% of prescriptions dispensed in the United States and save patients and the health care system hundreds of billions of dollars each year. Ensuring new generic medicines are approved and affordable depends on an efficient and well-resourced generic drug review program.

Why GDUFA IV matters: Reauthorizing GDUFA IV will provide FDA with the resources needed to continue reviewing generic drug applications efficiently, helping lower-cost generic medicines reach patients more quickly.



GDUFA IV will support timely access to safe and effective generic medicines.

Patients rely on generic medicines to manage acute and chronic conditions across nearly every disease area. FDA's rigorous review process ensures generic medicines meet the same standards for quality, safety and effectiveness as their brand-name counterparts.

Why GDUFA IV matters: GDUFA IV will help FDA continue conducting timely, science-based reviews while maintaining its high standards for safety and quality, ensuring patients have reliable access to the medicines they need.

GDUFA IV will improve access to complex generic medicines.

Complex generic medicines, like drug-device combinations, can expand treatment options and increase competition in areas where few alternatives exist. Efficient review of these products can help improve availability and affordability for patients.

Why GDUFA IV matters: Reauthorizing GDUFA IV will help FDA continue improving the review of complex generic medicines, supporting greater competition and expanding patient access to important therapies.

Disease-Specific Messaging

When communicating with FDA or Congress, organizations should complement these messages with information specific to their disease area. Consider including:

- The role generic medicines play in treating the disease.
- Current access or affordability challenges facing patients.
- Examples of how timely approval of generic medicines could improve care.
- Patient stories that illustrate the importance of maintaining an efficient generic drug review program.

Timeline of GDUFA IV

FDA/Patient Advocate consultations

September 17, 2026: GDUFA IV Reauthorization Proposed Enhancements Public Meeting

October 2025-March 2026	Fall 2026:	November 2026-January 2027:	January 2027-September 2027
FDA/industry negotiations	**Office of Management and Budget clearance**	**Public review of recommendations**	**Congressional Briefings**

July 2026: Draft package submitted for HHS clearance

October 17, 2026: Deadline for public comments and feedback on Sept. 17 meeting. Comments can be submitted via the Federal Register.

January 2027: Final package transmitted to Congress

September 2027: Enactment

Congressional passage must happen in 2027 before GDUFA III expires September 30, 2027.

What You Can Do

Participate in the September 2026 Public Meeting

- Join the FDA's public meeting on GDUFA reauthorization on September 17, 2026, from 9 a.m. to 2 p.m. ET. Meeting information can be found HERE.
- Register to attend virtually or in person. Registration is free. Register HERE.
- Register to provide public comment virtually or in person by 11:59 p.m. ET on September, 3, 2026. Register to provide public comment HERE.

Submit Comments to FDA

Following the final public meeting on September 17, FDA will open the public comment period. Comments can be submitted using this link HERE. Comments are open through October 17, 2026.

In the comment letter, include:

- Brief introduction to your organization
- Who you represent
- Why generic medicines matter for your community
- Disease-specific examples
- Why GDUFA IV should prioritize timely patient access
- Support for incorporating patient perspectives
- Any recommendations related to your disease area

More guidelines for public comments can be found HERE.

Engage with Congress

Key Congressional Committees will include:

- House Committee on Energy and Commerce
- Senate Committee on Health, Education, Labor, and Pensions

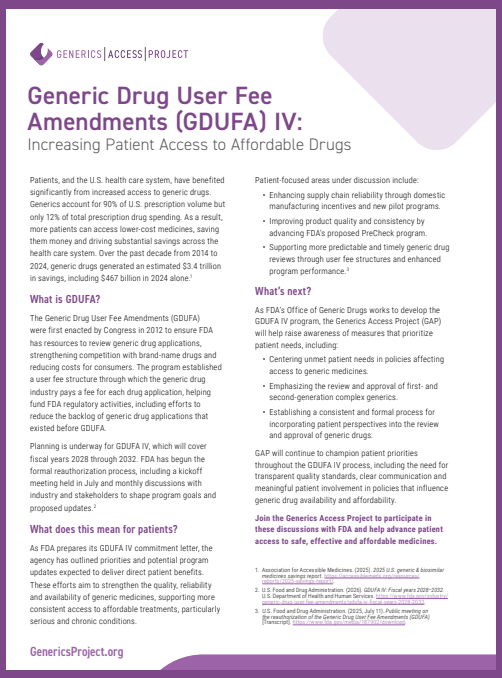
Contact Committee leadership and members with your comments.

In the letter, include:

- Introduce your organization.
- Describe the patients you represent.
- Explain why generic medicines matter.
- Include one or two patient stories.
- Ask Congress to support timely reauthorization of GDUFA IV before September 30, 2027.
- Thank the members for supporting policies that improve patient access to affordable medicines.

Helpful Resources

Generic Drug User Fee Amendments (GDUFA) IV: Increasing Patient Access to Affordable Drugs



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.

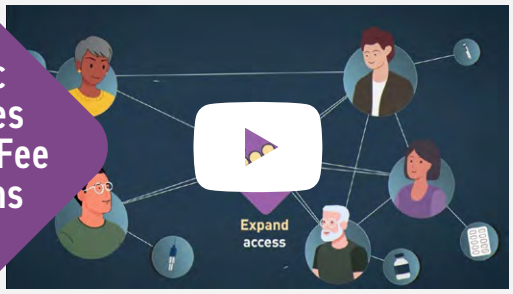
GAP will continue to champion patient priorities throughout the GDUFA IV process, including the need for transparent quality standards, clear communication and meaningful patient involvement in policies that influence generic drug availability and affordability.

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

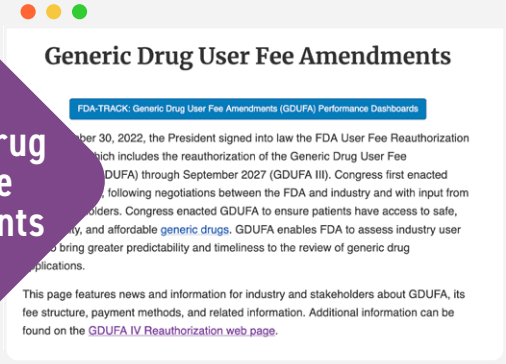
1. Association for Accessible Medicines. (2025). *2025 U.S. generic & biosimilar medicines savings report.* https://accessiblemeds.org/resources/reports/2025-savings-report/
2. U.S. Food and Drug Administration. (2026). *GDUFA IV: Fiscal years 2028–2032.* U.S. Department of Health and Human Services. 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/191354/download

GenericsProject.org

Generic Medicines and User Fee Programs



FDA Generic Drug User Fee Amendments



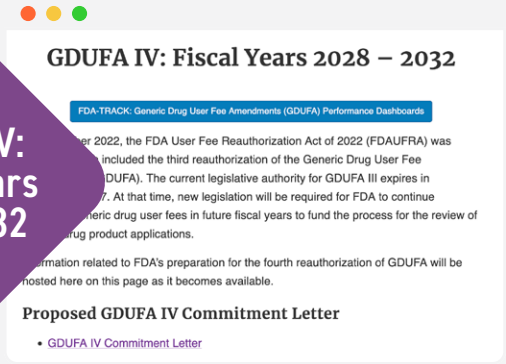
Generic Drug User Fee Amendments

FDA-TRACK: Generic Drug User Fee Amendments (GDUFA) Performance Dashboards

ber 30, 2022, the President signed into law the FDA User Fee Reauthorization hich includes the reauthorization of the Generic Drug User Fee DUFA) through September 2027 (GDUFA III). Congress first enacted following negotiations between the FDA and industry and with input from iders. Congress enacted GDUFA to ensure patients have access to safe, y, and affordable generic drugs. GDUFA enables FDA to assess industry user bring greater predictability and timeliness to the review of generic drug plications.

This page features news and information for industry and stakeholders about GDUFA, its fee structure, payment methods, and related information. Additional information can be found on the GDUFA IV Reauthorization web page.

FDA GDUFA IV: Fiscal Years 2028-2032



GDUFA IV: Fiscal Years 2028 – 2032

FDA-TRACK: Generic Drug User Fee Amendments (GDUFA) Performance Dashboards

er 2022, the FDA User Fee Reauthorization Act of 2022 (FDAUFRA) was included the third reauthorization of the Generic Drug User Fee DUFA). The current legislative authority for GDUFA III expires in 7. At that time, new legislation will be required for FDA to continue eric drug user fees in future fiscal years to fund the process for the review of ug product applications.

rmation related to FDA's preparation for the fourth reauthorization of GDUFA will be hosted here on this page as it becomes available.

Proposed GDUFA IV Commitment Letter

- GDUFA IV Commitment Letter

GENERICS | ACCESS | PROJECT

ABOUT THE GENERICS ACCESS PROJECT

The Generics Access Project advocates for policies that promote generic competition and efficient approval of generic medicines.

GenericsProject.org