PDUFA VIII TOOLKIT

FALL 2026

BACKGROUND

The Prescription Drug User Fee Act, or PDUFA, was first enacted by Congress in 1992 to ensure the FDA has resources to review prescription drugs and promote timely access for patients.

PDUFA frameworks have successfully allowed more patients to access prescription drugs by reducing the time it takes the FDA to review them.

PDUFA I (1993-1997)
Streamlined the approval process by introducing fees to the review process for patients to gain faster access to new drugs and biologics.

PDUFA II (1998-2002)
Added goals for procedures and processes along with increased funding to tighten review timelines.

PDUFA III (2003-2007)
Improved communication during initial reviews and supported limited prescription drug safety monitoring after approval.

PDUFA IV (2008-2012)
Modernized the pre-market review and post-market safety systems.

PDUFA V (2013-2017)
Strengthened regulatory science and post-market safety and set electronic data standards.

PDUFA VI (2018-2022)
Focused on establishing communication processes, improving financial management structures and enhancing the regulatory process for breakthrough therapy reviews.

PDUFA VII (2023-2027)
Incorporated allergenics and rare disease programs and enhanced operational procedures.

The Alliance for Patient Access supports the enactment of PDUFA VIII to maintain and expand patient access to affordable drugs.

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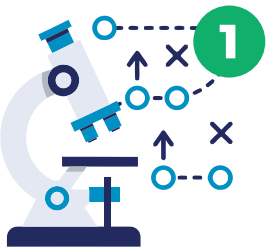
KEY MESSAGES

The Alliance for Patient Access supports the reauthorization of PDUFA VIII because it will help FDA ensure patients continue to have timely access to safe, effective and affordable prescription medicines. Organizations are encouraged to tailor these messages with examples from their own disease area and patient community.



PDUFA VIII will expedite pathways to the next generation of medicines.

Advancing the development of innovative treatments, including rare disease treatments and gene therapy programs, can give patients access to more treatment options. The growing demand for innovative treatments requires the FDA to strengthen drug review processes and implement best practices that support patients.

Why PDUFA VIII matters: PDUFA VIII will provide the FDA with the resources needed to meet the growing demands of patients by expediting the approval processes.

PDUFA VIII will create more predictable review processes for prescription drugs.

Patients need access to innovative, high-quality prescription medicines to manage acute and chronic conditions across every disease area. FDA's rigorous review process ensures prescription drugs are safe and effective for patients.

Why PDUFA VIII matters: PDUFA VIII will help FDA conduct predictable, science-based reviews to expand patient access and ensure safety.

PDUFA VIII will promote patient-focused drug development.

Patient perspectives can help shape prescription drug development to better meet patient needs. FDA's patient-focused drug development program provides a comprehensive approach for collecting and incorporating patient perspectives with case studies, public meetings and trainings.

Why PDUFA VIII matters: PDUFA VIII will help the FDA promote patient-focused drug development by incorporating patient experience and perspectives.

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

TIMELINE OF PDUFA VIII

FDA/patient advocate consultations

September 16, 2026: PDUFA VIII Reauthorization Proposed Enhancements Public Meeting

September 2027: Enactment

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 16, 2026: Deadline for public comments and feedback on Sept. 16 meeting. Comments can be submitted via the Federal Register.

January 2027: Final package transmitted to Congress

Congressional passage must happen in 2027 before PDUFA VIII expires September 30, 2027.

WHAT YOU CAN DO

PARTICIPATE IN PUBLIC MEETINGS

SEPTEMBER 16, 2026

- Register for FDA public meeting.
- Consider providing oral testimony.
- Share patient experiences whenever possible.

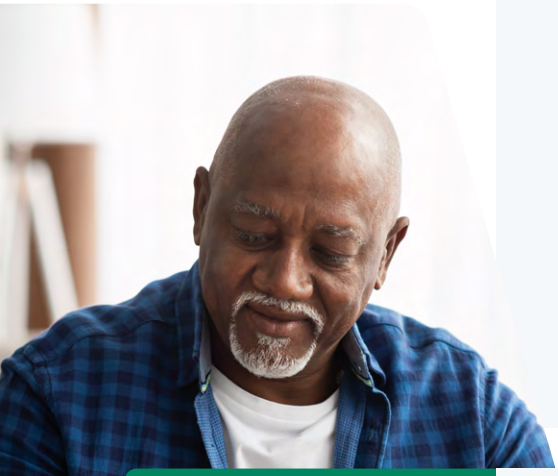
SUBMIT COMMENTS TO FDA

Following the final public meeting on September 16, 2026, FDA will open a public comment period. Submit comments through Regulations.gov. Check the FDA PDUFA VIII webpage for the docket number, submission instructions and deadlines.

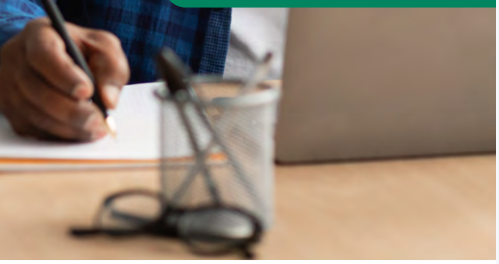
In the comment letter, include:

- An introduction to your organization and the patients you represent.
- An explanation of why prescription medicines matter.
- One or two patient stories.
- Disease-specific examples.
- Why PDUFA VIII 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:

- An introduction to your organization and the patients you represent.
- An explanation of why prescription medicines matter.
- One or two patient stories.
- Disease-specific examples.
- Ask Congress to support timely reauthorization of PDUFA VIII before September 30, 2027.
- A thank you to the members for supporting policies that improve patient access to affordable medicines.

HELPFUL RESOURCES

Prescription Drug User Fee Amendments (PDUFA):
Increasing Patient Access to Affordable Drugs

AUGUST 2025

FDA User Fee Programs

Millions of Americans rely on medications to treat their condition. All medications are reviewed by the U.S. Food and Drug Administration, or FDA, and only those that are determined to be safe and effective are approved for use. This process, however, can be time consuming and costly. In recent decades, Congress has established programs to help accelerate the approval process.

What Are FDA User Fees?

User fees are payments the FDA receives from manufacturers that make products such as drugs and medical devices. These fees are authorized by federal law and supplement the yearly funding the agency receives from Congress. The purpose of user fees is to support the FDA in carrying out its role of protecting public health, while ensuring that new, FDA-regulated products reach the market in a timely manner.

In Fiscal Year 2023, user fees funded approximately 75% of the total costs of the program, demonstrating their central role in sustaining the FDA's drug review capacity. The FDA has different user fee programs for the various types of products it oversees.

What are the Different User Fee Acts?

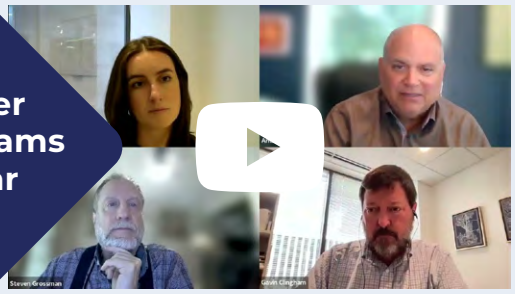
There are currently seven user fee acts. Each user fee act provides supplemental funding to the review process of several classes of treatments ranging from over-the-counter medications to medical devices, and even drugs for animals. The most common types of user fee applications are covered under the Prescription Drug User Fee Act, Generic Drug User Fee Amendments and Biosimilar User Fee Act.

> In Fiscal Year 2023, user fees funded approximately **75% of the total costs** of the program.

FDA Prescription Drug User Fee Amendments

FDA U.S. FOOD & DRUG ADMINISTRATION

AfPA FDA User Fee Programs Webinar



FDA PDUFA VIII: Fiscal Years 2028-2032

FDA U.S. FOOD & DRUG ADMINISTRATION

AfPA | Alliance for Patient Access

ABOUT THE ALLIANCE FOR PATIENT ACCESS

The Alliance for Patient Access is a national network of policy-minded health care providers advocating for patient-centered care.

@patientaccess @patientaccess Alliance for Patient Access

AllianceforPatientAccess.org