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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.

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What is the Prescription Drug User Fee Act?

Congress created the first user fee act in 1992. Known as the Prescription Drug User Fee Act, it is reauthorized every five years. This bill allows the FDA to collect fees from manufacturers of new prescription drugs.

Prior to this act, it took the FDA two and a half years to review medications. Today **it has been reduced to 10 months.**

The success of the Prescription Drug User Fee Act led to the creation of additional user fee programs like the Generic Drug User Fee Amendments and the Biosimilar User Fee Act.

What are the Generic Drug User Fee Amendments and Biosimilar User Fee Act?

The Generic Drug User Fee Amendments and the Biosimilar User Fee Act were established as part of the FDA Safety and Innovation Act of 2012. Generic medications contain the same active ingredients as their brand name counterparts but are typically offered at a lower price. A biosimilar drug is similar to a biologic medication, a drug made from natural and living sources, and has no clinically meaningful differences.

As their names suggest, these bills require manufacturers of generic and biosimilar drugs to pay fees that directly support the FDA's work. The fees also enable the agency to streamline the review processes for lower-cost alternatives to brand-name medications.



What is the Impact of FDA User Fees?

By providing dedicated funding streams, these programs help the FDA maintain robust staffing levels, improve review infrastructure, and manage a growing and diverse volume of drug applications. As a result, there has been a decrease in the average time it takes for new drugs and medical devices to move through the regulatory process. This acceleration allows patients to access new treatments much sooner.

These efficiencies support the agency's ability to meet performance goals, implement review standards, and maintain consistent oversight of drug quality and safety across different product categories.



Conclusion

FDA user fee programs allow for a more efficient drug review process. Reauthorization of these programs on a regular basis ensures that the FDA can carry out its public health mission effectively and without undue delays in the drug approval pipeline.



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