



GDUFA Reauthorization: A Primer

The U.S. Food and Drug Administration (FDA) plays a critically important role in making lower-cost, high-quality generic medicines available to patients. FDA reviews and approves abbreviated new drug applications (ANDA) submitted by generic drug manufacturers (ANDA sponsors). To receive FDA approval, data submitted in the ANDA must demonstrate the generic drug is pharmaceutically equivalent and bioequivalent to the Reference Listed Drug (RLD), more commonly known as the innovator or brand product.

What Is GDUFA?

Following the enactment of the Hatch-Waxman Act – the law that created the ANDA pathway – generic drug submissions to FDA grew substantially, straining FDA’s resources to review ANDAs on a timely basis. As a result, generic drug reviews were often sluggish and unpredictable.

Over time, FDA’s backlog grew to several thousand ANDAs, and the average time to approval exceeded 30 months, hampering patient access to quality, lower-cost generic medicines. To help ensure FDA continues to have sufficient resources to carry out its mission, Congress enacted the first Generic Drug User Fee Amendments (GDUFA) in 2012.

Nine out of every 10 prescriptions dispensed in the U.S. are generics.

In 2020 alone, the U.S. health care system saved **\$338 billion through the use of generic and biosimilar medicines.**

FDA’s generic drug review program is funded by a combination of congressional appropriations and user fees.

In 2020, GDUFA fees accounted for **70% of total program costs.**

GDUFA specifies various fees the agency sets and can collect from manufacturers, such as ANDA applications, Drug Master Files (DMF), and facility and program fees. In turn, the fees aid FDA’s ability to meet agreed-upon performance goals or commitments, such as timeline reviews and other regulatory activities. FDA also committed to providing annual reports to Congress on its performance.¹ The increases in transparency and communication are important to FDA’s ability to meet the commitments, which enhances the overall stability and predictability of the GDUFA program.

Over the course of GDUFA I and GDUFA II, the program has evolved. FDA and industry have worked together through key negotiated initiatives to increase efficiencies. The program

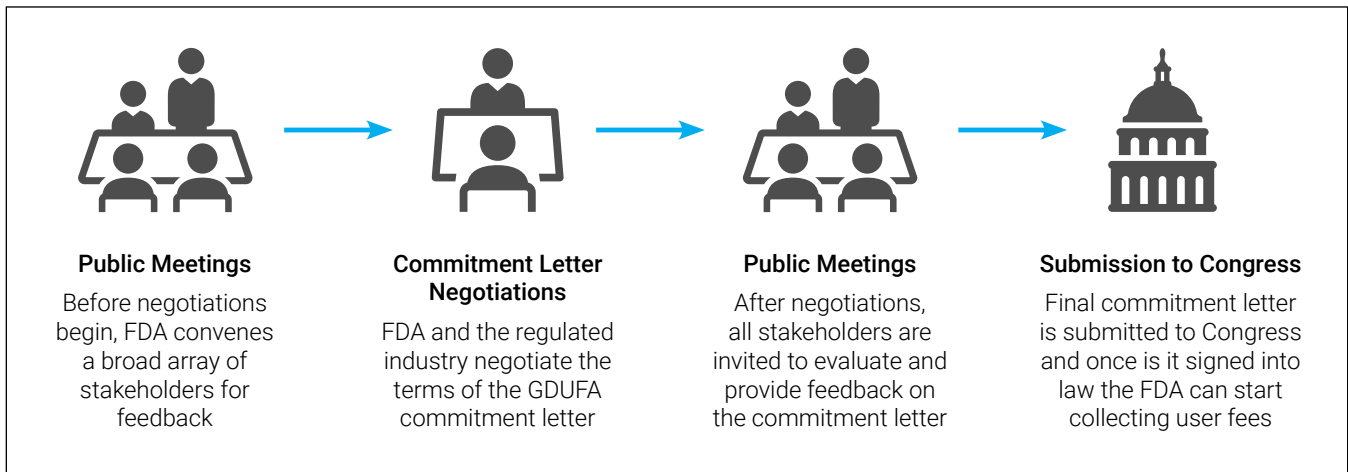
successes are measurable – FDA set approval records in fiscal years 2017, 2018 and 2019.²

1 FDA, GDUFA Performance Reports FY2015 – FY2020 ([link](#)).

2 Congressional Research Service, GDUFA Background and Reauthorization, April 2021 ([link](#)).

The GDUFA Reauthorization Process

GDUFA must be reauthorized every five years to allow FDA to continue collecting user fees to enhance the review of ANDA applications. The reauthorization process typically works as follows:



This thoughtful process results in carefully crafted GDUFA agreements that reflect input from a broad array of stakeholders. User fee reauthorizations also tend to enjoy strong bipartisan support due to the lengthy stakeholder input process before the contents are submitted to Congress.

The current GDUFA program is set to expire on October 1, 2022. A timely reauthorization is critical in allowing FDA to continue to carry out generic drug reviews and other important regulatory activities.

Recent Highlights

- **In FY20, FDA approved 737 ANDAs and tentatively approved 172 ANDAs**
- **In CY21, 80 first generics were approved**
- **Since 2018, 122 generics have been approved under the Competitive Generic Therapy pathway**

Key Components of GDUFA III

Advancing Approvals

- GDUFA III includes important commitments that will maintain the agency's rigorous ANDA review standards, building upon and improving the review process to increase timely patient access to high-quality, lower-cost generic medicines.
- For example, the newly negotiated provision known as "imminent action" will allow the FDA to miss a goal date if in FDA's judgement an approval or tentative approval of the application will occur shortly after. This commitment will mitigate the need to add additional review cycles unnecessarily and delay approvals over minor, easily resolvable issues.

Complex Generic Medicines

- Complex generics are generic versions of brand-name drugs that have complex active ingredients, routes of administration, drug-device combinations or formulations. These drugs are more difficult to develop due in part to the lack of FDA guidances.
- Congress and FDA helped spur competition for complex products by including provisions in previous UFA reauthorizations to increase product-specific guidances and meetings with FDA during the product development phase.
- GDUFA III builds on this success through commitments to facilitate the development of product-specific guidances for complex generic products – increasing transparency and understanding of FDA's expectations to allow for a more predictable review process.

Inspections

- The makers of generic and biosimilar medicines support FDA's inspections program. One of the original purposes of GDUFA was to provide resources for FDA to conduct facility inspections.
- Under the inspections process, FDA typically inspects a facility and identifies deficiencies. The facility has a specified timeframe to address and correct the identified deficiencies and subsequently request a reinspection from FDA.
- In some cases, extended time passes between when a facility performs the corrective actions to resolve the deficiencies and the time FDA is able to reinspect.
- Delays in reinspection lead to significant delays in the ANDA review process. GDUFA III advances the inspection process by helping ensure reinspection occurs within a specified timeframe.

Suitability Petitions

- Industry is required to submit a suitability petition to FDA prior to submitting an ANDA application for generic medicines that differ from the innovator product for the route of administration, strength or dosage form.
- Current law requires FDA to approve or deny suitability petitions within 90 days from petition submission. That deadline, however, is rarely met, delaying generic market entry.
- GDUFA III includes commitments and resources for new Full Time Employees (FTE) to facilitate the agency's ability to review suitability petitions. These new FTEs will help FDA meet GDUFA III commitments, including conducting completeness assessments within 21 days and using agreed upon metrics to prioritize petition reviews moving forward.

Sustainability of GDUFA Program Resources

- In GDUFA II, FDA committed to developing a Resource Capacity Planning (RCP) capability to optimize resources and better anticipate future resource needs.
- To further enhance the utility of the RCP, an additional tool was adopted in GDUFA III that would allow FDA to better forecast resource need from fiscal year to fiscal year via the Capacity Planning Adjustment (CPA).
- The CPA will help promote sustainability for both FDA and industry by allowing FDA to increase FTE needs as workload increases. In turn, the CPA will provide predictability for industry through a 3% cap to prevent significant fluctuation in fees year to year and minimize the financial barriers for smaller generic manufacturers.

FDA will hire 128 employees to carry out the GDUFA III commitments.

The number of employees needed to implement the user fee agreement is carefully negotiated and dependent on fee revenue available to the Agency from industry.