



October XX, 2026

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

RE: [Docket No. FDA-2025-N-0873] Reauthorization of the Generic Drug User Fee Amendments; Public Meeting; Request for Comments

[Submitted electronically via regulations.gov]

To whom it may concern:

The Generics Access Project (GAP), and the undersigned organizations, appreciate the opportunity to provide comments on the “Reauthorization of the Generic Drug User Fee Amendments; Public Meeting” (FDA-2025-N-0873).

GAP is a coalition of patient advocacy organizations across disease states who advocate for policies that promote generic competition and efficient approval of generic medicines. Generic medicines are a critical cost-lowering mechanism for patients and the healthcare system. Ensuring that patients have timely access to these affordable medicines is crucial.

Generic medications are an important resource in expanding access, as more affordable, effective treatment options for patients and the providers who treat them. These medicines make up about 91% of all prescriptions but only about 18% of the prescription spending.

The Generic Drug User Fee Amendments (GDUFA) have become an integral part to ensuring the timely approval of life saving generic medicines for patients, allowing more patients to have access to lower-cost treatment options, saving them money and driving down costs to the overall healthcare system.

GDUFA was first established in 2012, after the success of PDUFA, to help expedite the review and approval process and ensure safe and prompt access to generic medicines. The user fee program helped to establish greater predictability and timeliness in the generic drug review process and has helped to fund critical FDA capacity in generic drug assessment. Patients rely on generic medicines to manage conditions across nearly every disease area. The reauthorization of GDUFA IV helps the FDA continue conducting timely, science-based reviews while maintaining its high standards for safety and quality.

This is important for all generic medicines but particularly for the development of complex generics. Complex generics are generic drugs whose innovator products have features that make them harder to copy than other chemical medicines. The complexity of these drugs often means that there are fewer generic options that are available. These complex generics are especially important for those with chronic conditions.

The Federal Register notice identifies several important goals, including advancing approvals in fewer review cycles, supporting complex generic development, improving program efficiency, and facilitating domestic generic drug manufacturing. We encourage FDA to build on these proposals with a stronger focus on the patient experience.

- **Advance approvals in fewer review cycles.** The proposed GDUFA IV recommendations would update ANDA assessment timelines, improve communications, and address complex data issues with the goal of making the review process more efficient. We support these changes and encourage FDA to measure their success not only by review timelines, but also by whether they help patients gain access to new generic alternatives sooner.
- **Continue to prioritize complex generics.** The notice specifically proposes streamlined application-related meetings to support complex generic development. We support this direction and encourage FDA to give particular attention to complex generics where patients face high costs, limited alternatives, or access problems. Unmet patient need, lack of competition, affordability, and shortage risk should be considered when FDA identifies opportunities to facilitate development and review.
- **Build on FDA's existing patient and consumer consultation.** The notice notes that FDA consulted with patient and consumer advocacy groups during development of the proposed recommendations, consistent with the statutory requirement for periodic consultation. We encourage FDA to make patient engagement an ongoing part of GDUFA IV rather than limiting it to the reauthorization process. Patients, caregivers, and patient organizations should have regular opportunities to identify problems with generic availability, complex generics, shortages, and other barriers to maintaining treatment.
- **Establish a standing patient and consumer advisory mechanism.** As a practical extension of the consultation process already described in the notice, FDA should establish a standing GDUFA patient and consumer advisory mechanism. It should include patient organizations as well as individual patients and caregivers with relevant lived experience. Regular, structured input would give FDA a better understanding of how GDUFA policies affect patients in practice and provide a transparent way for that input to inform implementation.
- **Measure and report patient impact.** Finally, we encourage FDA to build patient-centered measures into the performance framework for GDUFA IV. In addition to review times and other operational measures, FDA should track outcomes such as generic

approvals, complex generic approvals, time to market availability, competition, and shortage trends. An annual patient impact report would help demonstrate whether GDUFA is achieving its ultimate purpose: improving patients' access to affordable, reliable generic medicines.

GDUFA will continue to play an important role in the timely approval of generic and complex generic medicines. Our organizations are committed to ensuring that the FDA has the resources they need to provide timely and reliable approvals for these lifesaving medications must continue to be a priority. Patients rely on these medicines as an affordable and efficacious treatment option, and their needs should remain central to the process moving forward.

Thank you for the opportunity to share our comments regarding the importance of the reauthorization of GDUFA IV to the patient advocacy community.

Should you have any questions, please contact Gavin Clingham at gavin@allianceforpatientaccess.org.

Sincerely,

The Generics Access Project

[Signed On Organizations]