



October 16, 2026

Submitted electronically via <https://www.regulations.gov/>

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

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

On behalf of the Healthcare Supply Chain Association (HSCA), which represents the nation's leading traditional healthcare group purchasing organizations (GPOs), we appreciate the opportunity to comment on the Food and Drug Administration's (FDA) proposed recommendations to Congress for Generic Drug User Fee Amendments (GDUFA) reauthorization for fiscal years 2028–2032 and the recent public meeting addressing these proposals. HSCA supports the FDA's continued commitment to ensuring a stable and affordable generic drug market and welcomes the opportunity to share our thoughts on how the reauthorization of GDUFA can better serve generics manufacturers, healthcare providers, and patients.

Traditional healthcare GPOs are the sourcing and contracting partners to hospitals, long-term care facilities, surgery centers, clinics, and other healthcare providers across the country. Traditional healthcare GPOs combine potential purchasing volume on behalf of healthcare providers, drive competition among suppliers, and reduce healthcare costs across the entire healthcare supply chain.

GPOs take a comprehensive approach to sourcing and contracting that considers not only the competitive price offered by suppliers, but also the quality and reliability of supply, which remain essential considerations for the integrity of the healthcare supply chain. In addition, GPOs carefully evaluate drug suppliers across a range of criteria, including the consistency of product availability, fill rates, recall frequency and management, disaster preparedness, secondary supply lines, and manufacturing transparency.

The FDA has identified manufacturing quality control issues as the primary cause of recurring generic drug shortages, as well as production delays, lack of raw materials, and manufacturer business decisions to discontinue products.¹ GPOs work to expand the number of suppliers in the market for essential products and life-saving medications, including generic medications. HSCA supports the FDA's goal of increasing the number of suppliers in the generic drug marketplace to ensure the delivery of safe and effective generic drugs to the public.

Patients have long relied on generic drugs to reduce costs and increase access to essential medications, but generic drug shortages continue to plague the health care industry, and no policy solution has thus far been able to mitigate the recurring problems. Children are also disproportionately impacted by drug

¹ The Food and Drug Administration, "Frequently Asked Questions about Drug Shortages," December 2024. <https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages>

shortages, as they often require limited or specialized medications that are more vulnerable to supply challenges.

Some generic manufacturers voluntarily and aggressively undercut their competition on price to gain hospital market share, driving competitors out of the market and significantly increasing the risk of shortages when manufacturers experience production issues. At the same time, generic drug manufacturers face barriers to entry, including GDUFA fees, costs and administrative barriers associated with investment in manufacturing, the challenge of proving bioequivalence, evolving patent issues, and uncertainty of projections on price and market share. Additionally, almost half the drugs in shortage, including generics, have just a single manufacturer, greatly increasing the likelihood of a shortage and underlining the need for incentives for innovation in this space.²

Traditional healthcare GPOs actively work to address these challenges, prevent drug shortages, and foster resiliency in the supply chain, but robust competition in the generic drug marketplace remains critical to ensuring a stable supply of generic drugs. Lack of competition increases the risk of drug shortages and supply chain disruptions. HSCA believes that the government can play a role in increasing the entry of generic drugs in medically critical areas with limited competition.

HSCA thanks the administration for the program enhancements included in the Proposed GDUFA IV Commitment Letter which ease barriers to entry into the generic drug market. HSCA recommends that the FDA's reauthorization of GDUFA also incentivize investment in quality and capacity, including the addition of secondary supply lines and having alternate or backup sources of active pharmaceutical ingredients (API), to support long-term access to generic medications. These incentives can be further enhanced for on-shore and near-shore manufacturing to increase domestic diversification.

Incentives structures should serve as complements to existing supply chain resilience strategies, and prioritize demonstrated manufacturing reliability, supply continuity, and meaningful redundancy, particularly for medically essential generic drugs and pediatric formulations that often have limited manufacturers and alternative sources.

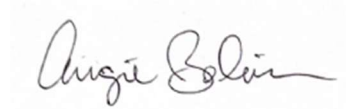
Additionally, the FDA should consider offering incentives to manufacturers for being the first or second generic entry into a market where the drug is actively in or at risk of shortage, and incentives for drugs with fewer than three active manufacturers, as well as medications that are deemed essential to patient care, including pediatric medications. Incentives could include:

- Exemption from GDUFA user and program fees (modeled after the Orphan Drug Act) targeted for manufacturers entering markets with limited competition or consistent shortages to encourage supply reliability;
- Streamlined submission of manufacturing data necessary for quality assessment;
- Faster review times;
- Exclusivity extensions triggered by the number of active manufacturers, without unnecessary delays to subsequent generic competition; and
- Accelerated consideration by the VA for formulary inclusion.

² American Society of Health-System Pharmacists, "NATIONAL DRUG SHORTAGES JANUARY 2001 - JUNE 2026," July 2026. <https://www.ashp.org/-/media/assets/drug-shortages/docs/Drug-Shortages-Report.pdf>

HSCA and its member GPOs appreciate the opportunity to offer our comments and recommendations. We look forward to continuing to work with the FDA to ensure that patients and providers have affordable access to high-quality generic medications. Please do not hesitate to contact me directly if HSCA can serve as a resource or answer any additional questions you may have. I can be reached directly at aboliver@supplychainassociation.org.

Sincerely,

A handwritten signature in dark ink, reading "Angie Boliver". The signature is fluid and cursive, with the first name "Angie" and last name "Boliver" clearly distinguishable.

Angie Boliver
President & CEO