



October 14, 2026

Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Reauthorization of the Prescription Drug User Fee Act; Public Meeting; Request for Comments Docket No. FDA-2026-N-8163, 91 Fed. Reg. 52702 (Aug. 14, 2026)

To Whom It May Concern:

This letter is submitted on behalf of the U.S. Chamber of Commerce (the "Chamber"), the world's largest business federation, representing businesses of all sizes, sectors, and regions. The Chamber strongly supports the timely reauthorization of the Prescription Drug User Fee Act ("PDUFA") and submits these comments to offer policy priorities for the PDUFA VIII commitment period (FY 2028–2032). PDUFA is the operational backbone of America's drug review system and a cornerstone of our health innovation advantage, and Congress must act to reauthorize it before the September 30, 2027, expiration of PDUFA VII.

I. Congress Must Reauthorize PDUFA VIII Without Delay

For more than 30 years, PDUFA has been a bipartisan success story, providing stability and continuity to the drug review program. When PDUFA was enacted in 1992, FDA averaged more than 29 months to review new drug applications, and 70% of new medicines were first approved outside the United States before American patients could access them. Today, the median approval time is 12 months for standard applications and 8 months for priority review, and approximately 70% of new medicines are now first approved in the United States. That transformation is a direct result of the resources, structure, and regulatory predictability that PDUFA provides.

User fees supplement, and by statute cannot replace, congressional appropriations to FDA's human drug review program. A lapse in user fee authority would risk longer review timelines, disruption to development pipelines, and delayed patient access to therapies

that in many cases have no alternative, with significant consequences for sponsors and the broader innovation ecosystem. The Chamber urges Congress to enact PDUFA VIII legislation well before the September 30, 2027, expiration of PDUFA VII.

II. Protect Review Performance and Improve First-Cycle Approval Rates

Predictable, timely review is the central promise of PDUFA. The Chamber supports the proposed third-party independent assessment of first-cycle review processes and FDA-sponsor communications. Too many complete response letters are issued for ultimately approvable applications, a pattern that delays patient access and imposes unnecessary costs on sponsors and the healthcare system.

A significant and underappreciated driver of these outcomes is manufacturing and facility-related issues. Such issues represent a leading cause of complete response letters and approval delays, even when clinical data are strong. The PDUFA VIII commitment letter directly addresses this challenge through introducing two new facility engagement meetings: a pre-submission meeting approximately 3 to 6 months before application submission, and a post-inspection meeting following a pre-approval facility inspection. These engagements give sponsors and FDA the opportunity to identify and resolve manufacturing issues before they become barriers to approval—a practical reform that the Chamber strongly endorses.

The Chamber also supports the commitment to prioritize the review of pivotal clinical trial protocols, enhanced transparency requirements for late-cycle information requests, and the commitment to provide labeling feedback 1 to 2 months prior to the PDUFA goal date. Together, these provisions reduce the risk of late-cycle surprises that can delay patient access to needed medicines. The Chamber urges FDA to act on the third-party assessment's findings promptly and transparently, and to treat improving first-cycle approval rates as a top programmatic priority throughout PDUFA VIII.

III. Mainstream Regulatory Science Tools and Embrace Modern Drug Development

The transition of PDUFA VII pilots, including Model-Informed Drug Development (MIDD), Rare Disease Endpoint Advancement (RDEA), Complex Innovative Trial Design (CID), and Real-World Evidence (RWE), into standard practice reflects the natural maturation of more than a decade of iterative work beginning with PDUFA V. Regulatory science tools should be part of routine FDA practice, not siloed in time-limited pilots. The Chamber commends this approach and urges FDA to ensure this transition broadens sponsor access to these tools without creating new bottlenecks.

The PDUFA VIII letter also continues support for rare disease drug development, including up to 10 RISE meetings and a corresponding public meeting to share learnings on regulatory science tools. Given the population-size challenges inherent in rare disease drug development, and the corresponding limitations on post-marketing study feasibility, the Chamber strongly supports the enhanced safety surveillance provisions in PDUFA VIII, including continued investment in Sentinel 3.0, which can support more efficient postmarket safety monitoring and evidence generation and increase the use of Sentinel to assess safety signals before imposing postmarket study requirements.

The Chamber further urges FDA to publish clear, actionable guidance on how modern tools, including artificial intelligence and machine learning, will be evaluated in regulatory submissions. Voluntary, risk-based frameworks that protect proprietary methodologies and preserve appropriate flexibility are essential to encouraging effective industry adoption and sustaining the private investment that drives innovation.

The Chamber encourages FDA to more consistently leverage accumulated scientific knowledge and existing evidence, including CMC, nonclinical, and clinical data, where scientifically appropriate. The Chamber welcomes the PDUFA VIII commitment to advance this approach across therapeutic contexts and encourages FDA to apply it broadly to reduce duplicative data generation and improve review efficiency.

IV. Fee Policy Must Reinforce U.S. Competitiveness

The Chamber strongly supports the proposed 50% application fee reduction for sponsors that anchor at least one Phase 1 clinical trial in the United States. This provision applies to applications including Phase 1 trials initiated after PDUFA VIII takes effect and preserves all existing core fee waivers and exemptions. It reflects sound policy: fee incentives should reinforce domestic investment and encourage more early phase trials to be conducted in the United States.

The Chamber also supports the restriction of small business fee waivers to U.S. applicants and the new 50% application fee requirement for the first non-orphan indication supplement for an approved orphan product. The United States must remain the premier destination for biopharmaceutical research and development across the full continuum, from early clinical trials through manufacturing and commercialization. The Chamber encourages Congress to build on these provisions and consider additional or alternative incentives that more broadly reward domestic early-stage development that would benefit companies already conducting Phase 1 trials in the United States.

V. Ensure Financial Accountability and Operational Efficiency

The Chamber supports the proposed Enterprise Performance Assessment and the associated third-party review of PDUFA program operations. User fees must be calibrated to FDA's actual resource needs. We support publishing the full assessment and requiring a documented rationale for any revenue adjustments. Annual financial transparency meetings with industry, with public minutes, are a meaningful accountability mechanism and should be maintained throughout PDUFA VIII.

The Chamber also strongly supports the dedicated PDUFA VIII funding to restore FDA reviewer staffing to appropriate levels following the significant workforce reductions of the past year. A well-resourced, effectively trained, expert review workforce is not ancillary; it is the foundation on which the drug review system depends. The Chamber supports the enhanced reporting provisions that will track staffing progress and provide accountability for the workforce commitments embedded in this agreement.

Finally, the Chamber supports the right-sizing of FDA's operating reserve and the mechanisms included in PDUFA VIII to align user fees with programmatic costs, including the reallocation of resources from discontinued programs such as the STAR Pilot. These provisions reflect the kind of fiscal discipline and long-term sustainability planning that the Chamber has consistently advocated for across federal programs.

VI. Conclusion

PDUFA VIII represents a measured step forward for the drug review program, one built on more than three decades of demonstrated success and continuous improvement. The Chamber urges Congress to act swiftly to reauthorize it, and urges FDA to implement its commitments in a manner that strengthens America's health innovation advantage, improves review predictability, and keeps the United States at the forefront of biopharmaceutical development. The Chamber looks forward to continued engagement with FDA and Congress throughout the reauthorization process and stands ready to provide additional information as needed.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lexi Branson', with a stylized flourish at the end.

Lexi Branson
Vice President, Health Policy
U.S. Chamber of Commerce