



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Finance Subgroup

February 5, 2026 | 1:00pm-3:00pm

FDA White Oak Campus, Silver Spring, MD

### MEETING PURPOSE

To address any remaining questions from Industry on FDA's financial framework proposals.

### PARTICIPANTS

#### FDA

Joshua Barton	CDER
Emily Ewing	CDER
Angela Granum	CDER
Kate Greenwood	OCC
Kristopher Hoover	CDER
Christine Hunt	OCC
Rebecca Kemp	CBER
Joshua Kirk	OO/OFBA
Andrew Kish	CDER
Stacy Yung	CDER

#### Industry

Rob Berlin	BIO (Vertex)
Steve Berman	BIO
Carl Garner	PhRMA (Eli Lilly)
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Drew Sansone	BIO (Alkermes)

### MEETING SUMMARY

The meeting focused on addressing key Industry priorities of establishing a mechanism for Shared Services transparency and identifying a method of evaluating efficiency on an ongoing basis. FDA indicated they could agree to expand the Shared Services reporting section of the five-year financial plan. The subgroup discussed the best approach to assessing productivities gained in the Agency.

### Follow Up Discussion

Continuing the discussion on FDA's financial framework proposal from the previous meeting, Industry emphasized the need for accountability in Shared Services funding. FDA responded by proposing enhanced transparency through detailed Shared Services reporting in the five-year financial plan. The five-year financial plan would include projections through the full authorization cycle and would continue to be updated every year with actuals. FDA emphasized

such reporting would address what is changing within the Shared Services organizations and how the Agency may continue to change. Industry requested FDA build out the previously provided scenario modeling tool to include payroll shifts to Shared Services. Industry asked about the process for deriving the Shared Services obligations baseline. FDA explained that the obligations line item is projecting FDA's needs based on its growing footprint, hiring needs, and consumption-based activities in the Agency that drive the size of Shared Services and how the programs contribute based upon their consumption of services. FDA detailed that Shared Services is billed proportionally based on consumption of activities and clarified that if Shared Services funding needed is less than expected, it would result in larger downward fee adjustments through the operating reserve mechanism, all else being equal.

The subgroup then transitioned to the topic of efficiency. Industry advocated for FDA finding efficiencies and creating transparency around a continuous improvement agenda, to include both review and Shared Services functions. FDA suggested that if the Agency has achieved efficiencies in Shared Services by the time the third-party study is conducted, the study would surface those productivities and contribute to possible adjustments to target revenue made in future years. FDA emphasized that any possible adjustment may be titrated over several years to maintain predictability in the base revenue. FDA reiterated that any adjustment would ultimately be FDA's decision.

Industry proposed a cap on the Capacity Planning Adjustment (CPA), in accordance with its overall goal of ensuring the sustainability of the program.<sup>1</sup> FDA stated the proposed cap was too low and that FDA's proposed cap was intended to be consistent with other user fee programs. The subgroup discussed historical growth rates and agreed to revisit the CPA in a future meeting.

Brief discussion occurred regarding FDA's proposal on charging fees for the first supplement that includes non-orphan indication(s) after the original application had been excepted from the application fee based on its orphan-only status. Industry indicated they listened carefully to the stakeholder feedback and explained their interest in encouraging innovation in rare diseases, and as such, Industry said they cannot accept FDA's proposal.

## **Wrap-Up and Next Steps**

The goals for the next meeting on February 10<sup>th</sup> are to be determined.

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<sup>1</sup> See the November 4th meeting summary for details on Industry's aims.