



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Finance Subgroup

November 18, 2025 | 3:30pm-5:00pm

Virtual Format (Teams)

### MEETING PURPOSE

To discuss the FDA proposal on fixing fee loopholes and plan for future subgroup meetings.

### PARTICIPANTS

#### FDA

Joshua Barton	CDER
Angela Granum	CDER
Emily Ewing	CDER
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

FDA and Industry discussed FDA's proposal on fixing fee loopholes. Industry does not believe the term "loophole" is an appropriate description of the existing provision. FDA and Industry agreed to further discuss the proposal in subsequent meetings.

FDA and Industry reviewed the status of each proposal presented by both sides and discussed the scheduling of topics for subsequent meetings. FDA and Industry agreed to continue this discussion in the next meeting on November 20<sup>th</sup>.

### Fixing Fee Loopholes

FDA presented its proposal to address a situation in which sponsors could be excepted from the application fee for an orphan-designated product and then later submit a supplement to expand the indication to non-orphan indications without ever paying the application fee and while continuing to be exempt from the program fee. FDA reiterated that it is not proposing any changes for applications or products with only orphan indications. FDA highlighted that, under

the current fee structure, fee exceptions and exemptions result in higher fees for the sponsors that do pay fees.

To respond to an Industry question in a prior meeting, FDA shared sales data for products that would be affected had this proposal been in place previously. FDA also shared that, due to other current limiting factors on the orphan exemption for program fees, FDA's assessment is that very few approved products would become eligible to pay program fees under this proposal because of having approved non-orphan indications.

Industry asked clarifying questions about how the process for assessing fee liability under this proposal may be implemented. FDA answered by detailing the relevant user fee assessment processes already in place and noted that any additional work resulting from this proposal would be minimal. Industry also asked about the nature and mechanism of the statutory changes that FDA would be proposing to enable this change. Further, Industry inquired whether stakeholders, including Congress, had been consulted regarding the proposed changes to incentives to rare disease drug development.

FDA and Industry agreed to revisit this proposal in a subsequent meeting.

### **Planning Session**

To support planning for the December meetings, FDA provided a summary of all proposals in the remit of the financial subgroup and the current state of discussion of each. As part of this summary, FDA reiterated, as it had stated in the previous meeting, that it would be unable to engage on Industry's proposals to eliminate the capacity planning adjustment (CPA) and to cap the inflation adjustment. FDA also reiterated that there may be alternative approaches Industry may consider pursuing, including considering opportunities for savings as a result of realizing administrative efficiencies.

Industry described a data request it planned to send to inform discussions regarding its goals related to the growth of the PDUFA program. FDA noted that it has shared a significant amount of data already and suggested that at this point focusing on negotiating proposals rather than requesting significant additional data may be more productive.

Industry reiterated the need to address CPA and inflation adjustment as part of a structured approach to help ensure the stability and long-term sustainability of the PDUFA program.

FDA again reiterated it is unable to engage on Industry's CPA and inflation adjustment proposals while suggesting a potential path forward that industry may consider pursuing.

Industry also noted that given the amount of organizational change the FDA had undergone in calendar year (CY) 2025, certain data needed to be provided to allow for a complete understanding of the current state of FDA staffing and resources related to the PDUFA program.

Industry requested time to caucus amongst their group members. FDA agreed.

After regrouping, FDA and Industry agreed to discuss how to proceed in the next meeting.

**Next Steps**

The goals for the next meeting on November 20<sup>th</sup> will be to determine a path forward and how to best proceed. In addition, the group would plan to review the technical change proposals from FDA.