Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

January 22, 2026 | 1:00pm–3:00pm

Virtual Format (Teams)

MEETING PURPOSE

To discuss hiring updates and internal controls, PDUFA VIII hiring, and an adjustment concept.

PARTICIPANTS

FDA		Industry	
Joshua Barton	CDER	Rob Berlin	BIO (Vertex)
Angela Granum	CDER	Steve Berman	BIO
Kate Greenwood	OCC	Carl Garner	PhRMA (Eli Lilly)
Kristopher Hoover	CDER	Kelly Goldberg	PhRMA
Christine Hunt	OCC	Kristy Lupejkis	PhRMA
Rebecca Kemp	CBER	Alison Maloney	PhRMA (Bayer)
Joshua Kirk	OO/OFBA	Drew Sansone	BIO (Alkermes)
Andrew Kish	CDER		
Stacy Yung	CDER		

MEETING SUMMARY

FDA provided additional information to address Industry questions on FDA pending hires and internal controls procedures. The subgroup discussed PDUFA VIII hiring. FDA presented a new concept for an adjustment to the financial framework.

Follow Up on Hiring and Internal Controls Questions

FDA provided updates on recent hiring activities, reporting that over 400 positions across the Agency have confirmed start dates, with many of these primarily for scientific review positions in CBER and CDER. FDA confirmed most hires, if not all, are external to the Agency. FDA indicated further rounds of hiring are expected.

Regarding internal controls, FDA clarified that the Agency maintains enterprise risk management procedures to surface any risk to programmatic goals and user fee commitments, in addition to the financial internal controls required under the Federal Manager's Financial Integrity Act (FMFIA).

PDUFA VIII Hiring Discussion

Industry raised concerns about resources issues raised in other subgroups. Both parties agreed this topic should be addressed at the Steering Committee level.

Adjustment Discussion

Recognizing an interest highlighted by Industry, FDA presented a new concept. FDA explained that consideration of this concept is dependent on Industry alignment with FDA's proposed approaches to the operating reserve adjustment (ORA), capacity planning adjustment (CPA), and inflation adjustment.

The concept is to establish an opportunity to assess efficiencies and to schedule a planned adjustment to the base revenue during PDUFA VIII, if warranted. This adjustment would be informed by an independent third-party study of efficiencies, workload, staffing, and other relevant factors. Informed by this study, the decision on whether and how to implement an adjustment would be FDA's, and the rationale for this decision would be published publicly. FDA noted that a possible outcome could be no adjustment.

Industry asked clarifying questions and FDA and Industry discussed different approaches to defining and measuring efficiencies. FDA noted that PDUFA has effectively utilized third-party evaluations for a long time because they can provide an objective external perspective on relevant issues.

Industry indicated they would take some time to reflect on the proposal and would like to discuss further in subsequent meetings.

Wrap-Up and Next Steps

The goal for the next meeting on January 27th will be to discuss next steps on the tracking, reserving, and reporting proposal, and to address Industry questions on the adjustment discussion. For more information on the tracking, reserving, and reporting proposal, reference the January 6th meeting minutes.