Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

January 08, 2026 | 1:00pm-3:00pm

FDA White Oak Campus, Silver Spring, MD and Virtual Format (Teams)

MEETING PURPOSE

To continue discussions on FDA's response to Industry's proposed financial framework, focusing on the operating reserve adjustment (ORA) and capacity planning adjustment (CPA).

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 presented a spreadsheet model demonstrating how the current operating reserve adjustment (ORA) structure would function in PDUFA VIII under different hiring and revenue scenarios. The subgroup agreed to further discuss the operating reserve adjustment once Industry had further examined the material presented. FDA shared their response to Industry's proposed framework on the CPA and provided an updated proposal.

Continue Discussion on FDA Response: Operating Reserve Adjustment

FDA presented example data to demonstrate how the current operating reserve adjustment (ORA) mechanism may function through the duration of PDUFA VIII as a backstop against potential excess collection of revenues compared with expenses under a variety of hypothetical staffing scenarios. FDA developed a spreadsheet model that enables testing of various circumstances and demonstrates the impact of the ORA and the annual target revenue.

Industry asked questions regarding the obligations assumptions in the model. FDA explained that the starting point used for the obligations in the model are the obligations numbers for FY 2026 and FY 2027 from the most recent published five-year financial plan and assumptions are used for the PDUFA VIII years. FDA clarified that the obligations numbers are assumptions used to create a model to demonstrate how the ORA would react under various circumstances; they are not actual planned numbers. Industry asked follow-up questions regarding what expenses would be included in the obligations line. FDA explained the legal framework that determines the PDUFA-allowable costs and referred to the annual financial reports, which document the actual obligations of PDUFA fee funds each year. Industry asked how FDA plans its fee obligations. FDA spoke to its internal planning and governance processes.

Industry asked further clarifying questions regarding the scenario model and the current revenue framework.

Capacity Planning Adjustment (CPA)

FDA stated that Industry's proposal as shared previously (which included a possibility for a negative CPA to account for efficiencies) was not feasible and, in its view, did not support shared FDA and Industry goals. FDA cited historical experience from PDUFA V, where the amount of funding from the Workload Adjustment could decline from year to year. FDA asserted that because of such fluctuations, finance personnel could not approve the use of what was seen as one-time funding for long-term payroll liabilities. This was resolved by the PDUFA VI negotiations and FDA expressed concern in returning to a system with such features. FDA emphasized that financial predictability is essential for the PDUFA program and introducing year-to-year uncertainty into base revenue would undermine this requisite predictability. FDA indicated it potentially could consider a reasonable cap on the CPA, as this would be consistent with FDA goals of standardization across user fee programs.

The meeting concluded with both parties agreeing to further discuss after Industry had the opportunity to further examine the materials presented.

Wrap-Up and Next Steps

The goals for the next meeting on January 13th will be to continue the discussion on FDA's response to Industry's funding framework.