Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

January 15, 2026 | 1:00pm-3:00pm

Virtual Format (Teams)

MEETING PURPOSE

To discuss FDA's responses to Industry questions and the inflation adjustment.

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 responses to Industry questions about hiring and budget processes and controls. FDA presented on the inflation adjustment methodology. Industry advocated for incorporating productivity and efficiency measures into the financial framework. Both parties agreed to continue these discussions in subsequent meetings.

Follow Up on Industry Questions

FDA responded to Industry questions regarding hiring timelines and financial controls. The first question focused on hiring timelines. FDA noted that while its aim is to hire as quickly as possible, many variables could factor into those timelines. FDA observed that there are over 400 people with confirmed start dates to join the Agency and other efforts to support additional hiring are underway. FDA noted that long-term growth personnel growth rates tended to be about 3% outside certain periods of focused growth, for example, during GDUFA I

when CDER experienced a hiring surge. FDA also noted that more recent years experienced higher growth rates which may have been influenced by the use of the Title 21 pay plan.

The second question was about budget processes and controls. FDA provided a comprehensive explanation of the legal framework governing user fee financial management. FDA reiterated that it is subject to appropriations law with PDUFA expenses legally limited to funds that have been appropriated and collected and to certain allowable costs as defined in statute. FDA detailed the rigorous government financial reporting requirements, financial controls, and audits the Agency is subject to, in addition to the reporting requirements detailed in the applicable statutory user fee provisions and commitment letters.

Inflation Adjustment

FDA noted that it is subject to inflationary pressure just like every other actor in the economy. FDA explained that the PDUFA program adjusts for inflation to maintain its basic purchasing power and that program stakeholders have recognized the need for PDUFA to account for inflation since at least 1998. FDA noted that the current version of the PDUFA inflation adjustment was adopted for PDUFA V after significant and detailed negotiations with Industry; it has since been adopted as the standard for use in other user fee programs. FDA emphasized that without the inflation adjustment, program purchasing power would gradually erode, creating challenges to maintaining stable operations that would be exacerbated over time. FDA presented comparative data demonstrating that the PDUFA inflation adjustment has been significantly less than other measures of inflation when compared to the cumulative changes since 2018.

Industry expressed its interest in incorporating efficiency and productivity measures into the PDUFA revenue framework. FDA observed its longstanding efforts to process improvement and efficiency to make the best use of available resources but expressed that changing the inflation adjustment is not an appropriate means to efficiency. Both parties agreed to continue discussions on these topics in subsequent meetings.

Wrap-Up and Next Steps

The goal for the next meeting on January 22nd is to be determined.