



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

January 06, 2026 | 3:30pm-5:00pm

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

MEETING PURPOSE

To discuss the PDUFA VIII ledger, review FDA's response to Industry's proposed funding framework, and examine technical details of the operating reserve adjustment mechanism.

PARTICIPANTS

FDA

Joshua Barton	CDER
Emily Ewing	CDER
Angela Granum	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 shared a financial ledger it developed, which is intended to track resource impacts of any agreements across subgroups. FDA shared some initial thinking in response to Industry's financial framework and proposed updates related to the operating reserve adjustment (ORA). Industry and FDA agreed to revisit the proposed updates to the ORA in the next meeting.

PDUFA VIII Ledger

FDA presented the PDUFA VIII ledger. This was developed to be a running tally of the financial impacts of any tentative agreements across subgroups.

FDA Response to Industry Framework

FDA acknowledged the substantial work invested by Industry in developing their proposal, while noting that some ideas presented significant implementation challenges. FDA articulated their understanding of Industry's core interests as ensuring appropriate funding is available when needed to support the appropriate staffing levels while preventing the potential use of payroll funds to be used for other PDUFA-allowable activities and/or holding fee funds that will not be utilized.

FDA outlined several fundamental requirements that any revenue structure agreement must satisfy for the PDUFA program to function as intended. Predictability emerged as the paramount concern, with FDA stating that funding levels must be stable and that this represents a core need recognized since PDUFA's inception in Fiscal Year 1993. FDA asserted that it cannot agree to a framework where base revenue is unpredictable. FDA also emphasized the importance of working towards standardization across user fee agreement programs.

Industry emphasized the need for flexibility to handle an increasingly dynamic external environment to ensure a stable and sustainable program. FDA cautioned against changing the fundamental tenets of the PDUFA revenue structure, as it had been thoughtfully and purposely designed by FDA and Industry over previous negotiations. FDA suggested that updates can be made to manage new challenges but highlighted that extensive changes to the program could introduce new risks or unintended consequences. FDA believed it would be helpful to talk through the practical operations of the current revenue-setting process to ensure a technically sound discussion when considering any changes.

Operating Reserve Adjustment (ORA)

FDA provided example scenarios. FDA noted Industry's concern that payroll funds could be diverted to other PDUFA-allowable activities and/or holding fee funds that will not be utilized. FDA believes this concern can be addressed more effectively with the existing revenue structure without tinkering with the program by introducing unnecessary changes and new risks.

FDA proposed an update focused on implementing a tracking, reserving, and reporting system for potential personnel compensation and benefits (PC&B) underspending, if any. This proposed three-component approach would establish tracking of review staff positions to be restaffed, set aside funds for remaining backfills in the operating reserve, and establish clear reporting on any reserved funds in annual financial reports. FDA noted that under its proposal those set-aside funds would contribute to the operating reserve and as such, if the operating reserve were to exceed the maximum balance allowed in statute, there would be a downward ORA that would reduce fees. FDA emphasized its view that this proposal aligns with both Industry and FDA goals and adds transparency and accountability features, without modifying the fundamentals of the program. The conversation concluded with FDA agreeing to further build out the example scenarios for the duration of PDUFA VIII.

Wrap-Up and Next Steps

For the next meeting on January 8th, the subgroup will continue discussions on the proposed updates to the operating reserve adjustment and revisit the capacity planning adjustment.