Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

March 3, 2026 | 3:30pm-5:00pm

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

MEETING PURPOSE

To discuss FDA's response to Industry's most recent document with final proposals.

PARTICIPANTS

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

MEETING SUMMARY

FDA and Industry discussed the supplemental proposals Industry suggested in their 'Finance Path Forward' document to strengthen the financial model. FDA asked clarifying questions and provided perspectives on Industry's ideas.

FDA's Response to Industry's 'Finance Path Forward'

Industry began the meeting by noting the significant progress the subgroup had made in crafting a financial framework that met Industry and FDA's shared goal to ensure appropriate funding is available and is utilized to enable FDA to restaff review and re-envision support functions and continue to grow, if needed, within realistic bounds to secure the long-term stability and sustainability of the PDUFA program. Industry stated their intent is to increase transparency and understanding of the program for improved visibility into and comprehension of where user fee funds are directed and how they are used. FDA conveyed

their agreement with Industry's priorities of increased understanding, collaboration, and transparency.

FDA inquired how Industry would suggest additional guardrails would be implemented to ensure user fee funding in the operating reserve tracking, reserving, and reporting (OR TRR) set-aside and Shared Services would be used solely to hire and retain staff for the process for review of human drug applications. Industry stated they sought FDA's guidance on the best path forward to create these protections. FDA reiterated that the foundation for the ORA TRR concept would be in statute, and that Shared Services would be subject to additional transparency in the PDUFA Five-Year Financial Plan. Industry and FDA then discussed how PDUFA VIII resource agreements could be realized.

The subgroup transitioned to Industry's recommendations around the capacity planning adjustment (CPA) and the operating reserve. Industry reiterated its proposal that, if the third-party study recommended that an enterprise performance adjustment (EPA) be made, and if FDA declined to make such an adjustment, FDA would not be able to take a CPA as part of the PDUFA user fee-setting process for the following fiscal year. FDA asked questions to clarify the intent and the problem this proposal would address. Industry and FDA discussed hypothetical scenarios to determine the feasibility and desirability of this proposal.

FDA then referenced the decreased 9 – 11-week operating reserve range proposed by Industry as part of the 'Finance Path Forward'. FDA remarked that the 10 – 12-week operating reserve range previously discussed within the subgroup was in support of the Agency's user fee program standardization objective and that any further decrease in the cap would undermine this objective. FDA and Industry agreed to bring additional considerations to the next meeting.

Industry spoke to their proposal for FDA to commit to regular technical staff meetings each year on fee-setting and financial topics. In Industry's view, these meetings would create a continuous engagement model and ensure understanding and support of FDA decision-making. FDA indicated an openness in principle to have technical staff meetings with Industry. FDA noted, however, that it would not be able to discuss non-public information related to fee-setting prior to the publication of the fee-setting Federal Register Notice. Industry stated their understanding of these considerations. FDA relayed it would give the request further thought.

Next Steps

The goal for the next meeting is for FDA to respond to Industry's final set of proposals.