Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

March 19, 2026 | 1:00pm-3:00pm

Virtual Format (Teams)

MEETING PURPOSE

To review updates to the PDUFA VIII ledger, and to discuss the draft of the finance section of the commitment letter, additional direct costs, and the revenue setting process.

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		

MEETING SUMMARY

FDA and Industry reviewed updates to the PDUFA VIII ledger. FDA answered Industry questions on the finance section of the commitment letter draft. FDA and Industry discussed some outstanding costs. FDA offered a method for setting the base revenue in Fiscal Year (FY) 2028 and presented two options for calculating net full-time equivalents (FTEs).

PDUFA VIII Ledger

FDA provided a revised version of the ledger, reflecting recent decisions across subgroups.

Discuss Finance Section of Commitment Letter Draft

FDA answered clarifying questions from Industry on the finance section of the commitment letter draft and the proposed approach to enhanced reporting. Industry indicated they will send more substantive edits and comments in writing.

Costs Discussion

FDA presented estimated recurring costs for time reporting licenses.

FDA provided cost estimates for four third-party assessments negotiated in PDUFA VIII by the Finance, Pre-Market, and Chemistry, Manufacturing, and Controls (CMC) groups. FDA stated funding for all studies would be a one-time cost in FY 2028. The subgroup noted that the estimates are based on the current draft commitment letter language for the third-party studies and any changes to this language may require updated cost estimates.

FDA addressed Industry clarifying questions.

Revenue Setting Process

FDA raised technical considerations for the subgroup to consider. The first topic was the base revenue setting: FDA presented an approach where an exact dollar amount could be written into statute to represent FY 2028 base revenue, made possible due to the timing of the negotiation cycle and the known adjustments that will roll forward into FY 2028.

The second topic was accounting for the net FTEs: FDA displayed two ways of doing so, noting that the options have the same resulting amount. One option would be to work the FTE costs into the base revenue for FY 2028, which would simplify the fee-setting process and streamline the statute by removing the additional dollar amounts step. The second option would be to maintain the existing Additional Dollar Amounts step in the fee-setting process. FDA reiterated that both options effectively achieve the same outcome, but the first option is slightly simpler as it removes a step. Industry stated they will reflect on the meeting discussion and follow up with comments.

Next Steps

The goal for the next meeting is to be determined as informed by Industry follow-up comments.