Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

April 2, 2026 | 1:00pm-3:00pm

Virtual Format (Teams)

MEETING PURPOSE

For Industry to ask questions about the drafted finance commitment letter materials provided by FDA.

PARTICIPANTS

FDA		Industry	
Joshua Barton	CDER	Rob Berlin	BIO (Vertex)
Emily Ewing	CDER	Steve Berman	BIO
Kate Greenwood	OCC	Carl Garner	PhRMA (Eli Lilly)
Kristopher Hoover	CDER	Kelly Goldberg	PhRMA
Christine Hunt	OCC	Alison Maloney	PhRMA (Bayer)
Rebecca Kemp	CBER	Lucy Vereshchagina	PhRMA
Andrew Kish	CDER		

MEETING SUMMARY

Earlier in the week, FDA sent documents with an updated table that could be included in the Annual Financial Report as well as details on how calculations for how the fee-setting process would work in PDUFA VIII. After reviewing the document, Industry had questions regarding: the inflation of additional direct costs, the timing of the step-down of the operating reserve cap from 14 weeks to 12 weeks, the inclusion of budget authority figures in the enhanced reporting tables to be included in the PDUFA Annual Financial Report, and the calculation for detailee payroll.

Industry Questions

Industry noted that in the draft materials sent by FDA, the time reporting licenses had been incorporated into the base revenue for PDUFA VIII, remarking that in previous reauthorizations, the licenses were listed as additional direct costs. FDA explained the Agency's belief that the time reporting licenses are an integral part of the financial system and thereby do not need to be discussed every reauthorization cycle and therefore would be best incorporated into the base revenue amount. FDA agreed, however, to Industry's request to keep the time reporting licenses

to be represented in the additional direct cost adjustment rather than in the base revenue amount.

Industry expressed surprise that the direct costs in the final ledger were inflated in a way that did not reflect the explicit agreements reached in the negotiation subgroups. FDA asserted that these calculations were done in accordance with statutory requirements and had been calculated this way since the inception of PDUFA. FDA explained that the additional direct costs have had their own inflation adjustment in statute since PDUFA VI, per Industry request in prior negotiations, and displayed the current authorized section of statute that requires these costs to be inflated each year. FDA also noted that every version of the ledger that included dollar amounts for direct costs throughout negotiations had included a footnote indicating that direct cost amounts sum to amount written in statute for fiscal year (FY) 2027 pre-inflation. FDA demonstrated how the amounts being negotiated summed to the amount in statute prior to negotiation.

Industry emphasized their perspective that direct cost amounts written into statute should reflect the negotiated amounts without inflation. FDA said it would take this back and follow up with more information.

Industry asked about the approach to lowering the operating reserve cap from 14 weeks to 12 (14 weeks in FY 2028, 13 weeks in FY 2029, and 12 weeks for FY 2030 and subsequent years). Industry stated they had expected to see the cap for FY 2028 at 13 weeks, not 14 weeks. FDA noted that if the operating reserve cap was changed to 13 weeks for FY 2028 fee setting, and the Agency was rehiring at a consistent rate, the result may be a very large downward operating reserve adjustment in FY 2028 and perhaps close to no downward operating reserve adjustment in FY 2030. In other words, Industry should be prepared to expect the target revenue to rise rapidly over the first few years of the next authorization cycle. Industry stated they understood this possibility. FDA stated it would need to consult with its financial leadership before responding.

Industry asked FDA for clarification as to why the budget authority (BA) amounts could not be included in the enhanced reporting table, as Industry requested. FDA stated that adding BA values for these object class codes would be challenging for several reasons: the annual Financial Report to Congress is required by the Hill to address fee spending, thereby focused on fee dollars, and adding the BA values would change the scope of the report. FDA added that the BA values are also already available in many Agency budget materials. FDA also mentioned concern that adding BA values could create inconsistencies across financial reports, because FDA is required to submit an annual financial report for all its user fee programs.

Industry asked FDA to provide detail on how the detailee payroll was calculated. FDA demonstrated, from the spreadsheet models provided in February, that these figures were determined by taking the total detailees in CDER and CBER by office and then applying the PDUFA-funded percentage to derive a PDUFA funded full-time equivalent (FTE) count. Industry asked what could change with the detailee payroll over the next two years that could be detrimental to the target setting for the operating reserve tracking, reserving, and reporting agreement. FDA stated that since the TRR payroll target number is fixed, there will be no impact

once the detailees are reassigned to Shared Services. Industry and FDA discussed various scenarios to validate the static nature of the payroll target.

Next Steps

FDA stated they are drafting the revenue setting pieces of statutory language and will send the proposed language to Industry as soon as possible. Industry said they are reviewing the materials as they receive them.