



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Finance Subgroup

March 24, 2026 | 3:30pm-5:00pm

Virtual Format (Teams)

### MEETING PURPOSE

To allow Industry an opportunity to respond to the previous week's discussion, to discuss the finance commitment letter draft, and to give an update on the PDUFA Five-Year Financial Plan.

### PARTICIPANTS

#### FDA

Joshua Barton	CDER
Angela Granum	CDER
Kate Greenwood	OCC
Kristopher Hoover	CDER
Christine Hunt	OCC
Rebecca Kemp	CBER
Joshua Kirk	OO/OFBA
Andrew Kish	CDER

#### Industry

Wade Ackerman	PhRMA (Covington)
Rob Berlin	BIO (Vertex)
Steve Berman	BIO
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Drew Sansone	BIO (Alkermes)

### MEETING SUMMARY

Industry indicated they accept the estimated costs for the third-party assessments and the time reporting licenses. Industry and FDA discussed the draft finance section of the commitment letter: Industry would like to see further detail on payroll and obligations in the financial report. FDA presented a summary of the 2026 update to the PDUFA Five-Year Financial Plan.

### Industry Response to Previous Discussion

Industry indicated they agree to the estimated costs for the four third-party assessments negotiated in PDUFA VIII by the Finance; Pre-Market; and Chemistry, Manufacturing, and Controls (CMC) groups. The subgroup noted that there has been no negotiated change to the current draft commitment letter language for the third-party studies, thus the provided estimates are current. Industry stated they also agree to the costs for time reporting licenses for PDUFA VIII. Regarding the prior discussion around accounting for the net full-time equivalents

(FTEs) as part of the base-setting described in the statutory language, Industry indicated they need more time to consider the options before making a determination.

### **Discuss Finance Commitment Letter Draft**

Industry elaborated on their comments provided on the finance section of the commitment letter draft. Industry asked about the “benefits former personnel” line included in the proposed enhanced reporting table. FDA reiterated its assertion that benefits to former personnel has always been an allowable cost<sup>1</sup> and allowable costs will not be changing in PDUFA VIII. Industry indicated they were assessing trends in this object class code to understand what values may be reported in the future and apply a consistent level of interpretation. FDA replied that these obligations depend on staff attrition levels and cannot be predicted with any certainty. Industry and FDA agreed this topic could be brought to the technical meetings in PDUFA VIII agreed upon by this subgroup.

Industry asked for further breakdown to see pay and non-pay costs in more detail, including budget authority as well as user fee obligations. FDA stated it would consider Industry’s request and come to the next meeting with further thoughts. Industry emphasized they are hoping to see consistency in the reports provided by FDA to enable better comprehension.

### **PDUFA Five-Year Financial Plan Update**

FDA noted that the 2026 update to the PDUFA Five-Year Financial Plan had been published and provided a brief overview of topics relevant to the negotiations. FDA answered Industry’s clarifying questions.

### **Next Steps**

Industry reiterated they are reviewing the draft finance section of the Commitment Letter and will provide further feedback as soon as is feasible. FDA stated they are drafting statutory language and will send the proposed language to Industry as soon as possible.

The subgroup agreed to hold a planning call to determine the topics for the next meeting.

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<sup>1</sup> For more details of the discussion of this topic, reference the 2/24/26 meeting minutes.