



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

January 13, 2026 | 3:30pm-5:00pm

Virtual Format (Teams)

MEETING PURPOSE

To address Industry questions regarding the operating reserve adjustment model and scenarios presented by FDA last Thursday.

PARTICIPANTS

FDA

Joshua Barton	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 and Industry met to address questions about how the current operating reserve adjustment (ORA) would function in PDUFA VIII in a variety of staffing circumstances. FDA committed to providing detailed responses to Industry's questions at the next meeting.

Continue Discussion on Operating Reserve Adjustment (ORA) Scenario Model

Industry asked questions after reviewing the operating reserve adjustment scenario modeling developed by FDA. Industry stated that their primary goal is to ensure that funds are directed effectively toward drug reviews. Industry emphasized they seek to establish a financial framework that can ensure long term sustainability of the PDUFA program in a dynamic environment.

Industry asked about the feasibility of FDA's aim to restaff reviewers and other PDUFA-funded positions. FDA indicated its expectation is to restaff as quickly as possible. Industry also sought further clarification about how user fee obligations are planned, noting that user fee obligations

levels have a direct impact on the operating reserve, and therefore the operating reserve adjustment calculation. FDA highlighted that the tracking, reserving, and reporting proposal introduced in last week's meetings is intended to mitigate Industry concerns. Industry asked for more information on how the tracking, reserving, and reporting that FDA is proposing would be assured.

Industry also inquired about PDUFA-funded full-time equivalents (FTEs) outside of CDER and CBER, as well as the application of the inflation adjustment in the FDA model.

FDA committed to following up on staffing and internal controls questions in more detail in subsequent meetings.

Wrap-Up and Next Steps

The goals for the next meeting on January 18th will be to provide comprehensive responses on the questions raised by Industry and to discuss the inflation adjustment.