



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Finance Subgroup

January 29, 2026 | 1:00pm-3:00pm

Virtual Format (Teams)

### MEETING PURPOSE

To discuss Industry edits to meeting minutes, review specific numbers for the operating reserve adjustment tracking, reserving, reporting (ORA TRR) approach, and assess conceptual alignment on the PDUFA VIII financial framework.

### 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
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)

### MEETING SUMMARY

The subgroup discussed edits to meeting minutes and reviewed FDA's proposed ORA TRR approach. Both parties agreed to focus the next meeting on discussing the proposed ORA TRR approach in a greater level of detail.

#### Industry Edits to Meeting Minutes

FDA and Industry discussed comments and edits made to meeting minutes.

#### Operating Reserve Adjustment (ORA) Tracking, Reserving, Reporting (TRR) Details

FDA presented the number of review staff positions funded by PDUFA that have been vacated voluntarily and, as such, would be restaffed for the purposes of the operating reserve adjustment

(ORA) tracking, reserving, reporting (TRR) proposal. (See minutes for January 6 and January 8 for more details on this proposal). FDA presented previously shared staffing data to represent what the Agency believes is an appropriate hiring target. Industry inquired about where non-review positions would be reflected in the proposed ORA TRR approach. FDA explained their intention is that the previous discussion regarding potential savings for administrative efficiencies would address these positions. During the discussion, FDA and Industry noted that they had different interpretations of the proposal and agreed that further discussion is needed. The subgroup agreed to further discuss these proposals in subsequent meetings.

### **Industry Perspective on Alignment**

Industry again expressed support for enhancing the PDUFA VIII financial framework to allow for FDA to be appropriately staffed. The subgroup agreed upon both the importance of achieving a shared understanding of the proposed ORA TRR approach and aligning on if the ORA TRR proposal is the path forward and can be further negotiated before re-engaging on detailed negotiations on other topics within the remit of the financial subgroup.

### **Wrap-Up and Next Steps**

The goals for the next meeting on February 3<sup>rd</sup> will be to discuss a proposed process for the ORA TRR in a greater level of detail to help elucidate areas of alignment and areas requiring additional discussion.