

# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Premarket Subgroup

January 13, 2026 | 1:00 pm-3:00 pm

Virtual Format

### MEETING PURPOSE

To discuss draft commitment letter language for FDA’s Advancing Real-World Evidence (RWE), Industry’s Enhancing Transparency and Consistency Related to Patient Experience Data (PED), and FDA’s Model-Informed Drug Development (MIDD) proposals. To discuss Industry’s Facilitate First Cycle Reviews proposal.

### PARTICIPANTS

#### FDA

Mary Thanh Hai	CDER
Emily Ewing	CDER
Thamar Bailey	CDER
Marie Bradley	CDER
Irene Chan	CDER
Sonday Kelly	CDER
Andrew Kish	CDER
Phillip Kurs	CDER
Rajanikanth Madabushi	CDER
Janet Maynard	CDER
Jennifer Mercier	CDER
Paul Phillips	CDER
Katie Rivers	CDER
John Scott	CDER
Issam Zineh	CDER

#### INDUSTRY

Mark Taisey	BIO (Amgen)
Annetta Beauregard	BIO
Rob Berlin	BIO (Vertex)
Steve Berman	BIO
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Adora Ndu	BIO (Bridge Bio)
Katrin Rupalla	PhRMA (J&J)
Drew Sansone	BIO (Alkermes)
Derek Scholes	BIO
Lucy Vereshchagina	PhRMA

### MEETING SUMMARY

FDA and Industry discussed draft commitment letter language for the Advancing RWE, Enhancing Transparency and Consistency Related to PED, and MIDD proposals. Industry presented a summary of the previous Improve FDA-Sponsor Interactions and Meetings Management negotiation. FDA presented a response to Industry’s Facilitate First Cycle Reviews subproposal to post all redacted action packages.

### **Approach to Advancing RWE Draft Commitment Letter Language**

Industry presented proposed revisions to the draft commitment letter language FDA prepared. FDA asked clarifying questions about Industry's proposed revisions, which Industry addressed. FDA agreed to review Industry's proposed revisions in further detail and respond to them at a future meeting.

### **Approach to Enhancing Transparency and Consistency Related to PED Draft Commitment Letter Language**

FDA presented draft commitment letter language for the Enhancing Transparency and Consistency Related to PED proposal. Industry stated that it had a few suggested revisions and would provide its feedback at the next meeting.

### **Approach to MIDD Draft Commitment Letter Language**

FDA presented a response to Industry's proposed revisions to the MIDD draft commitment letter language. Industry responded with suggested modifications to the revised language FDA proposed. After further consideration, FDA stated it would share updated draft commitment letter language at the January 20<sup>th</sup> meeting.

### **Approach to Facilitate First Cycle Reviews Proposal**

FDA presented a response to Industry's subproposal requesting that the Agency post redacted action packages of all PDUFA New Molecular Entity (NME) and non-New Molecular Entity (NME) New Drug Applications (NDAs), Biologics License Applications (BLAs), and efficacy supplements within 30 calendar days of approval. FDA focused on Industry's proposal to post redacted action packages of efficacy supplements in its presentation.

FDA emphasized the Agency's workload involved with redacting and posting action packages along with fulfilling Freedom of Information Act (FOIA) requests. FDA also presented data on the increasing volume of efficacy supplements approved in the past ten years. FDA stated that Industry's proposal for the Agency to proactively post redacted action packages within 30 days of approval of efficacy supplements is not feasible, as the estimated volume is well over 200 efficacy supplements approved per year and this work would be in addition to other proactive postings and FOIA requests responses the Agency must complete.

Industry asked clarifying questions about the Agency's timeframe for posting action packages and whether certain redaction requests are prioritized over others. FDA clarified the Agency's timeframe for posting action packages and noted that Agency staff redact action packages alongside other workstreams, such as litigation work.

Industry asked whether the Agency has considered using Artificial Intelligence (AI) as a starting point for redactions and about the number of Agency staff available to redact action packages. FDA stated that AI is being piloted in low-risk categories such as short reports. However, the Agency is not using AI in NMEs or efficacy supplement action package postings, as these are much larger documents comprised of hundreds of pages and place the Agency at greater risk of disclosing confidential commercial information, trade secrets, or personal privacy information that could result in negative impacts that could include consequences for individual FDA staff or release of company secrets.. FDA provided further clarification on the number of Agency staff who work on redactions. FDA noted that any additional hires would require approximately two years to train to become experienced redactors. FDA stated that for negotiations to continue on this proposal, Industry would need to narrow the scope of efficacy supplements to be considered, increase the length of time from approval to posting, provide resources to increase FTEs, and agree to no performance goal metrics.

Industry stated it would review FDA's presentation in further detail and bring feedback to a future meeting. FDA agreed to provide further clarification on whether the Agency's timeframes for posting action packages reflect past performance or goals. FDA will also seek clarity on whether the FTEs responsible for FOIA requests are also working on the postings of CR letters.

### **Next Steps**

The goals for the next meeting on January 15<sup>th</sup> will be to discuss FDA's Rare Disease proposal, Industry's Facilitate First Cycle Reviews proposal, and draft commitment letter language for Industry's Enhancing Transparency and Consistency Related to PED proposal.