



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

December 4, 2025 | 3:30pm – 5:00pm

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To present FDA’s proposed changes to the Information Technology section of the PDUFA VII commitment letter and share updates from the subgroups.

PARTICIPANTS

FDA

Andrew Kish	CDER
Emily Ewing	CDER
Mary Thanh Hai	CDER
Amy Ramanadham	CDER
Larry Lee	CDER
Josh Barton	CDER
Issam Zineh	CDER
Sonday Kelly	CBER
Christine Hunt	OCC
Kate Greenwood	OCC

INDUSTRY

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

MEETING SUMMARY

FDA summarized their proposed approach to the Information Technology (IT) section of the commitment letter for PDUFA VIII. The FDA and Industry subgroup leads then provided a summary of their subgroup’s accomplishments from this week and their plans for upcoming weeks.

FDA Proposal: Information Technology

FDA shared their proposal to streamline the IT section of the commitment letter by not including in the PDUFA VIII commitment letter reference to activities that are standard operations and removing modernization activities that have already been completed or are in progress under

PDUFA VII. FDA's proposal maintains acknowledgement of key activities that FDA staff will remain dedicated to, including engaging in international consortia and maintaining staff expertise in bioinformatics, computational biology information, and Digital Health Technologies (DHTs). FDA noted that the Agency is centralizing its IT functions and acknowledged the rapid rate of innovation in IT. FDA also noted that the Agency is proposing to discontinue the direct costs agreed to for IT commitments in PDUFA VII.

Industry stated that they need additional time to review FDA's proposal. Industry said that they find the quarterly meetings that FDA holds with Industry to discuss PDUFA VII IT commitments helpful and noted that FDA's proposal does not include those meetings. FDA said that the Agency can consider including touchpoints. Industry committed to providing additional feedback on FDA's proposal. Industry said they are optimistic that FDA can leverage IT to help with workload.

Subgroup Progress Updates

The FDA and Industry subgroup leads from the Pre-Market; Post-Market Safety; Chemistry, Manufacturing, and Controls (CMC); and Finance subgroups, as well as the Steering Committee, summarized their accomplishments and plans for next steps. The subgroups continued detailed discussions of specific topics, and three new tentative agreements were reached. For additional details about the subgroup meetings, please see the meeting minutes for those subgroups.

Next Steps

The tentative goal for the next meeting on December 9th will be to review FDA's proposed approach to the Cell and Gene Therapy section of the commitment letter.