



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

December 9, 2025 | 9:30am – 10:30am

Virtual Format

MEETING PURPOSE

To present FDA’s proposed changes to the Cell and Gene Therapy section of the commitment letter.

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
Drew Sansone	BIO (Alkermes)
Derek Scholes	BIO
Mark Taisey	BIO (Amgen)
Donna Boyce	PhRMA (Pfizer)
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 Cell and Gene Therapy (CGT) section of the commitment letter for PDUFA VIII. Industry asked clarifying questions and agreed to provide feedback on FDA’s proposed approaches to CGT and Information Technology (IT) at future Steering Committee meetings.

FDA Proposal: Cell and Gene Therapy

FDA acknowledged the focus on Cell and Gene Therapy (CGT) in PDUFA VII and the resources that FDA received under PDUFA VII to strengthen staff capacity in CGT. FDA shared that the Agency's PDUFA VIII proposal for CGT is to use existing staff to continue work related to CGT. FDA also proposes to streamline the CGT section of the commitment letter by removing one-time commitments that are in progress or have been completed (e.g., guidance, workshops). FDA also noted that the Agency is proposing to discontinue the direct costs agreed to for CGT commitments in PDUFA VII.

Industry inquired about whether FDA's proposal includes continuation of training for reviewers and external outreach related to CGT. FDA noted that FDA intends to use the resources provided in PDUFA VII to continue training and outreach activities. Industry stated that they need additional time to review FDA's proposal, and Industry committed to providing additional feedback on FDA's proposal.

Next Steps

The goal for the next meeting on December 11th will be to share progress updates from the subgroups. Industry agreed to let FDA know when Industry is ready to share feedback on FDA's proposed approaches to Cell and Gene Therapy and Information Technology.