



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

March 3, 2026 | 9:30am – 10:30am

FDA's White Oak Campus, Silver Spring, MD and Virtual Format

MEETING PURPOSE

To plan for the remainder of PDUFA VIII negotiations.

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)
Drew Sansone	BIO (Alkermes)
Derek Scholes	BIO
Mark Taisey	BIO (Amgen)
Carl Garner	PhRMA (Eli Lilly)
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Lucy Vereshchagina	PhRMA

**This participant attended virtually.*

MEETING SUMMARY

FDA recapped FDA and Industry's progress in PDUFA VIII negotiations so far and the time dedicated to negotiations. FDA shared that FDA and Industry have dedicated about the same amount of time to PDUFA VIII negotiations as was dedicated to PDUFA VII negotiations. FDA also reviewed the list of proposal topics for which FDA and Industry still need to reach agreement. FDA and Industry acknowledged a shared commitment to concluding negotiations as soon as possible.