



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Steering Committee

May 15, 2026 | 10:00am – 10:30am

Virtual Format

### MEETING PURPOSE

To conclude technical negotiations and confirm next steps.

### PARTICIPANTS

#### FDA

Andrew Kish	CDER
Emily Ewing	CDER
Mary Thanh Hai	CDER
Amy Ramanadham	CDER
Josh Barton	CDER
Issam Zineh	CDER
Christine Hunt	OCC
Mahesh Ramanadham	CDER

#### INDUSTRY

Annetta Beauregard	BIO
Rob Berlin	BIO (Vertex)
Steve Berman	BIO
Derek Scholes	BIO
Mark Taisey	BIO (Amgen)
Donna Boyce	PhRMA (Pfizer)
Carl Garner	PhRMA (Eli Lilly)
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Glen Murphy	CHPA (Kenvue)
Carolyn Herrmann	CHPA
Marcia Howard	CHPA
David Spangler	CHPA
Erin Oliver	CHPA (Haleon)

### MEETING SUMMARY

FDA and Industry confirmed that this meeting confirms the end of technical negotiations. FDA reviewed the next steps for reauthorization, which include ratification by FDA and Industry, clearance through the Department of Health and Human Services and the Office of Management and Budget, public comment, re-clearance, and transmittal to Congress.

FDA and Industry thanked each other for the collaboration and time that both parties dedicated to PDUFA negotiations.