



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry CMC Subgroup

February 12, 2026 | 9:00am -10:15am

Virtual Format

### MEETING PURPOSE

To address clarifying questions about FDA and Industry Chemistry, Manufacturing, and Controls (CMC) review process enhancement proposals.

### PARTICIPANTS

#### FDA

Sau (Larry) Lee	CDER
KaLonna Maull	CDER
Don Henry	CDER
Mahesh Ramanadham	CDER
Lisa Harlan	CDER
Denise Gavin	CDER
Francis Godwin	CDER
Emily Ewing	CDER
Danielle Villata	CDER
Rebecca Frey-Cooper	CDER
Derek Smith	CDER
Ivy Sweeney	CDER

#### Industry

Carl Garner	PhRMA (Eli Lilly)
Ryan Kaat	PhRMA
Drew Sansone	BIO (Alkermes)
Kelly Goldberg	PhRMA
Derek Scholes	BIO

### MEETING SUMMARY

Industry shared that they were not ready to discuss feedback on FDA's proposed meeting mechanics. FDA and Industry discussed their approach to continuing certain commitments from the CMC section of the PDUFA VII commitment letter in the PDUFA VIII commitment letter.

### PDUFA VII Commitment Letter Review

FDA and Industry shared perspectives on the CMC section of the PDUFA VII commitment letter, with the intent of identifying language to keep, modify, or remove for PDUFA VIII. FDA noted that most of the PDUFA VII commitments are time-bound, one-time commitments that were successfully completed and do not need to be continued, and Industry generally agreed. Industry

suggested maintaining language around implementing best practices learned from the PDUFA VII commitments and continuing training when needed. FDA and Industry agreed to discontinue the Chemistry, Manufacturing, and Controls Development and Readiness Pilot (CDRP) Program at the end of PDUFA VII.

FDA and Industry also discussed the “Enhancing Inspection Communication” section of the PDUFA VII commitment letter, and Industry indicated a preference for continuing to include language about FDA’s goal to communicate its intent to inspect a facility at least 60 days in advance. FDA stated the Agency will consider this language and how it may be incorporated with the facility lifecycle approach being negotiated for PDUFA VIII.

### **Next Steps**

FDA and Industry agreed to consider how to incorporate the inspection communication language in PDUFA VII to PDUFA VIII and revisit the discussion at a future meeting. The goal for the next meeting on February 17, 2026 is to discuss Industry’s feedback on the proposed meeting mechanics and revisit the inspections communication language.