Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

March 10, 2026 | 10:30am -11:15am

Virtual – Microsoft Teams

MEETING PURPOSE

To address clarifying questions about FDA and Industry Chemistry, Manufacturing, and Controls (CMC) commitment language.

PARTICIPANTS

FDA		Industry	
Sau (Larry) Lee	CDER	Carl Garner	PhRMA (Eli Lilly)
Mahesh Ramanadham	CDER	Ryan Kaat	PhRMA
Denise Gavin	CBER	Derek Scholes	BIO
Emily Ewing	CDER	Drew Sansone	BIO (Alkermes)
Rebecca Frey-Cooper	CDER	Kelly Goldberg	PhRMA
Francis Godwin	CDER		
Don Henry	CDER		
KaLonna Maull	CDER		
Lisa Harlan	CDER		
Ivy Sweeney	CDER		

MEETING SUMMARY

FDA reviewed feedback and edits to the draft of CMC commitment letter language from the Agency. Both FDA and Industry discussed their rationale and provided clarification to questions.

Draft Commitment Letter Language

The Agency reviewed several structural edits to enhance overall document clarity and flow. Both parties agreed to simplify language for the third-party assessment and public workshop in the commitment letter as there will be a detailed analysis design included in the contractor statement of work. Both parties also established that a mutual accountability framework is key, recognizing that program success requires effective execution by both FDA and Industry partners.

Next Steps

FDA and Industry will make the edits discussed and conduct final reviews of this section.