



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

March 5, 2026 | 10:30am -11:00am

Virtual – Microsoft Teams

MEETING PURPOSE

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

PARTICIPANTS

FDA

Sau (Larry) Lee	CDER
Mahesh Ramanadham	CDER
Denise Gavin	CDER
Emily Ewing	CDER
Rebecca Frey-Cooper	CDER
Francis Godwin	CDER

Industry

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

MEETING SUMMARY

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

Draft Commitment Letter Language

The Agency reviewed revisions to word choices, sentence structure, and section placement. Both parties discussed limiting review clock extensions to situations where timing absolutely requires it and permitting only one extension per application to prevent abuse of the process.

The Agency reviewed their reframing of the third-party assessment. This assessment would include conducting a workshop, analyzing the program data, and providing recommendations for potential program improvements.

Next Steps

The goal for the next meeting on March 10, 2026 is to address final questions and provide additional clarity on the drafted commitment letter language.