



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

February 19, 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
Don Henry	CDER
Mahesh Ramanadham	CDER
Lisa Harlan	CDER
Denise Gavin	CDER
Emily Ewing	CDER
Rebecca Frey-Cooper	CDER

Industry

Carl Garner	PhRMA (Eli Lilly)
Ryan Kaat	PhRMA
Derek Scholes	BIO

MEETING SUMMARY

FDA agreed with Industry’s proposal to maintain the “Enhancing Inspection Communication” language from PDUFA VII in the PDUFA VIII commitment letter, with some added context to situate the inspection notification process with the facility lifecycle approach. FDA and Industry briefly discussed meeting timelines for the post inspection meeting.

Revisit Inspections Communications Language

At the meeting on February 17th, Industry indicated their preference for including language in PDUFA VIII that mirrors the PDUFA VII language about FDA’s intent to notify sponsors of an inspection. FDA agreed to retain the language and suggested that the language be included with an overview of FDA’s lifecycle approach to facility management in PDUFA VIII.

Facility Lifecycle

Post Inspection Meeting

FDA indicated that it needs more time to consider meeting timelines for post inspection meetings. FDA indicated that details for special cases (e.g., inspections conducted late in the review cycle) may be discussed in guidance or via the proposed public workshop to be completed as part of an assessment of the facility lifecycle approach.

Next Steps

The goal for the next meeting on February 24th, 2026 is to begin discussing FDA's proposed commitment letter language. FDA and Industry agreed on a share goal of concluding CMC negotiations in early March.