Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

February 5, 2026 | 9:00am -10:15am

FDA White Oak Campus, Silver Spring

MEETING PURPOSE

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

PARTICIPANTS

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

MEETING SUMMARY

FDA shared feedback on Industry's proposed list of potential topics that should be within the scope of the pre-submission facility meeting. FDA and Industry discussed resources required to implement the proposed pre-submission facility and post inspection meetings. FDA and Industry also agreed to exclude the PDUFA VII Chemistry, Manufacturing, and Controls Development and Readiness Pilot (CDRP) Program from PDUFA VIII.

Facility Lifecycle

Pre-Submission Facility Meeting

FDA and Industry reaffirmed that there is general agreement about the focus for the pre-submission facility meeting, which would be to discuss high-risk facility issues that could impact

approvability. FDA emphasized the need to keep the pre-submission facility meeting focused on facility needs in the context of strategy discussion, as relevant to a specific application.

Industry reviewed their proposed list of potential topics that would be in scope for the pre-submission facility meeting. FDA agreed that some topics, such as prior inspection activity of manufacturing sites, supply chain nodes (i.e., a set of facilities that will potentially be used to support a future application) and strategies to reduce risks, and novel or unique process elements of facility operations relevant to manufacturing of the drug, would be in scope for the proposed pre-submission facility meeting.

FDA asserted that information regarding manufacturing process development, validation plans, manufacturing schedules, and data submission should be out of scope for the proposed meeting and should be discussed via the existing meeting types outlined in FDA guidance; however, Industry may provide awareness of manufacturing schedules. FDA also asserted that use of alternative tools to assess facility information, inspection scheduling, and overall novel or unique manufacturing processes are out scope for the pre-submission facility meetings.

Resources

In response to a request from Industry, FDA clarified the resources required to implement the facility lifecycle proposal currently being negotiated (i.e., the proposed pre-submission facility and post inspection meetings). Industry shared that understood FDA's resource request and noted that they would share the resource request with the Finance subgroup.

PDUFA VII Commitments

FDA and Industry agreed that the CDRP Program initiated in PDUFA VII, and the resources associated with the Program, would not continue under PDUFA VIII.

Next Steps

The goal for the next meeting on February 10, 2026 is to discuss mechanics of the proposed pre-submission facility meeting, including timelines, meeting type, and meeting materials. Time permitting, FDA and Industry will also begin discussing meeting mechanics for the post inspection meeting.