Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

February 3, 2026 | 10:30am -12:30pm

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		

MEETING SUMMARY

FDA presented a diagram of the proposed approach to pre-submission facility and post inspection meetings and responded to questions from Industry. FDA and Industry discussed details and key processes associated with each meeting.

Facility Lifecycle Diagram

FDA presented a diagram of how the proposed pre-submission facility and post inspection meetings would fit into the review program. Industry agreed that the diagram reflected their general understanding of what FDA and Industry have discussed so far.

Post Inspection Meeting

FDA stated that for post inspection meetings, FDA would issue a Form 483 following the inspection, and the facility would respond to the Form. FDA would review the response and determine whether any facility issues are approvability issues. If there are facility-related

approvability issues, FDA would intend to inform the applicant of any such issues. The applicant could then submit a post inspection meeting request, which FDA could approve or deny based on whether the request meets criteria for the meeting. FDA would provide appropriate documentation and touchpoints following the meeting. Industry noted that the process appeared reasonable. Industry inquired about the timelines that would be associated with post inspection meetings (i.e., response time, scheduling time) and expressed that post inspection meetings should not always result in goal date extensions. FDA and Industry agreed that more discussion is needed around meeting timelines and the triggers for goal date extensions.

Pre-Submission Facility Meeting

FDA acknowledged that Industry shared a proposed list of potential topics that should be within the scope of the pre-submission facility meeting, and FDA committed to providing a response at a subsequent meeting.

Industry highlighted that pre-submission facility meetings could inform FDA's risk assessment for facilities and the timing of inspections. FDA shared that inspection scheduling is a complex process, in which FDA considers, among other things, facility location and looks across applications that use the facility.

FDA and Industry also discussed the purpose and timing of the pre-submission facility meeting. Industry indicated that three to six months before application submission would typically be appropriate for holding a pre-submission facility meeting, and FDA generally agreed. FDA and Industry also agreed that the pre-submission facility meeting should focus on facility topics with relevance to the application and should not be used to discuss CMC review or to replace the Phase 2 CMC meeting. FDA expressed concern that some applicants may be unwilling to disclose facility challenges, and Industry countered that applicants may be willing to share if transparency helps avoid a late-cycle Complete Response.

Next Steps

The goal for the next meeting on February 5, 2026 is to continue discussing operational details associated with the proposed pre-submission facility and post inspection meetings and to discuss how to approach existing sections of the PDUFA VII commitment letter.