Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

November 12, 2025 | 1:00pm -3:00pm

Virtual - Microsoft Teams

MEETING PURPOSE

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

PARTICIPANTS

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

MEETING SUMMARY

The meeting discussion was focused on FDA's responses to questions received from Industry pertaining to FDA's Manufacturing Prior Approval Supplement (PAS) Timeline and Facility Lifecycle proposals. The conversation also covered Industry's updated proposal slides.

Prior Approval Supplement (PAS) Timelines

FDA reviewed inspection data related to PAS submissions. FDA highlighted the percentages of applications requiring domestic and foreign inspections, respectively, that received a complete response letter. FDA also reviewed average inspection timelines for standard versus expedited submissions. There were additional conversations focused on the processes and steps that contribute to coordinating and finalizing inspection activities.

Facility Lifecycle

FDA shared preliminary thoughts on where they believe Industry could benefit most from the Facility Lifecycle proposal. Industry noted the potential need for guidance on regulatory expectations for the different elements of the proposal.

FDA reviewed CDER and CBER data around the timing of pre-approval and pre-licensing inspections relative to the PDUFA goal date, indicating: (1) product specific inspections are happening generally in the middle – late middle of the review cycle (month 6-8) and (2) inspection timing is not always predictive of complete response (CR) letter rate. FDA indicated its perspective that the facility issues that led to a CR letter were significant, such that they could not be resolved during the review cycle.

FDA shared additional details around the intention for each element of the proposal. Industry asked FDA to describe their proposed measures of success for this proposal, and FDA responded by providing some possible examples including potential reduction in the number of CR letters due to facility issues, better utilization of alternative tools, etc.

Industry Proposal Slides

Industry noted that their proposals are focused on enhancing communications to ensure the applicant and FDA are on the same page about any approvability issues related to manufacturing facilities. FDA shared its position that many facility issues would be better addressed in elements described in the FDA's facility lifecycle proposal, including post-inspection meetings. Industry highlighted a need to understand what is feasible from FDA in terms of communicating inspection findings and identifying opportunities to communicate more.

Next Steps

The goals for the next meeting on November 18, 2025, include FDA responding to the written data requests and meeting questions received from Industry. FDA will also provide more details relating to the Facility Lifecycle proposal. Lastly, FDA plans to ask additional questions relating to Industry's proposals.