Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

November 18, 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)
Mahesh Ramanadham	CDER	Kelly Goldberg	PhRMA
Lisa Harlan	CDER	Steve Berman	BIO
Francis Godwin	CDER		
Rebecca Frey-Cooper	CDER		
Emily Ewing	CDER		
Denise Gavin	CBER		

MEETING SUMMARY

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

Prior Approval Supplement (PAS) Timelines

FDA reviewed PAS data from the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), respectively. FDA shared PAS receipt totals by year for New Drug Applications (NDA) and Biologics License Applications (BLA), including the count of drug shortage applications and applications requiring a foreign inspection. FDA also outlined how many applications per year required a foreign inspection and the average time to complete the inspection. Additional data for inspections that led to a Complete Response (CR) letter with the foreign inspection as the only CR reason was reviewed. The Agency suggested that the

additional review time, as outlined in the proposal, could allow the facility and the applicant to resolve deficiencies leading to a CR.

Facility Lifecycle

FDA shared data related to the total number of CDER submissions that reference Type 5 Facility Drug Master Files (DMF). Next, the Agency outlined details and proposed benefits for each of the key elements of the Facility Lifecycle Proposal and explained how, in the Agency's view, these elements collectively addressed industry's concerns regarding facilities and inspection issues that could lead to a CR. FDA noted that the proposed steps offered in the proposal would depend on the scenario and needs of the applicant, and that the intention is the applicant could request individual steps in the proposal on a case-by-case basis. Industry asked clarifying questions around the various steps and how the stated goals of the proposal could be tracked, measured, and captured in any commitment letter. Industry responded to the Agency's question about perceived challenges with the current Establishment Inspection Report (EIR) process. Industry noted that the Form FDA 483 may not give explicit clarity on the specific issues identified that may impact approvability, and that issues that are documented in the EIR might provide a broader context and awareness of those issues that may impact the approvability of applications. Therefore, Industry requested clarity and consistency on when they will receive the EIR.

Next Steps

The goals for the next meeting on December 2, 2025, include Industry providing their feedback or interest on continuing negotiating the Manufacturing PAS Timeline proposal and FDA reviewing what draft commitment language and proposed changes in the statutory language could look like to include and support the key elements in the Facility Lifecycle proposal.