Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

November 4, 2025 | 11:00am -12:30pm

FDA White Oak Campus, Silver Spring

MEETING PURPOSE

To introduce and address clarifying questions about FDA and Industry 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	Derek Scholes	BIO
Lisa Harlan	CDER	Kelly Goldberg	PhRMA
Francis Godwin	CDER	Lucy Vereshchagina	PhRMA
Emily Ewing	CDER		
Denise Gavin	CBER		

MEETING SUMMARY

The meeting discussion was focused on exploring FDA and Industry's PDUFA VIII CMC manufacturing and inspection interests. Basic ground rules, best practices, and meeting logistics were also reviewed. FDA reviewed proposals focused on prior approval supplement timelines and facility lifecycle topics. FDA acknowledged that after reviewing Industry proposals, there were some elements related to facilities/inspections included in the pre-market subgroup slides that should be discussed within the CMC group.

Prior Approval Supplement (PAS) Timelines

FDA proposed a tiered approach where there would be a different review clock for prior approval supplements based on priority and if the inspection would be domestic or foreign. FDA noted the potential for more consistency and predictability with this approach, in addition to more time for industry to resolve issues that are found after inspection. Industry asked for clarity around FDA's internal process to prepare for inspections.

Facility Lifecycle

FDA proposed an approach to facility readiness that included proactive engagement opportunities for applicants and facilities with the agency and the modification of statutory language to enable the utilization of funds in support of certain pre-submission facility-related activities to potentially de-risk application review. Industry asked for clarity around fee funding for this proposal and where in the timeline for early engagement FDA believes would be most impactful.

Next Steps

The goals for the next meeting on November 12, 2025, will be for both FDA and Industry to share feedback about the current proposals and gain clarity around what has been shared. In addition, the Industry CMC-related proposals referred from the Pre-Market subgroup will be discussed. Industry's pre-market slides include proposals related to inspection notifications and communications.