Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

December 2, 2025 | 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	
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	Derek Scholes	BIO
Emily Ewing	CDER		
Denise Gavin	CBER		

MEETING SUMMARY

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

Prior Approval Supplement (PAS) Timelines

Industry shared thoughts and noted that they did not see enough benefit, over the status quo, to agree to FDA's PAS Timeline proposal. FDA's initial proposal included a 3-Month Priority Track goal date for drug shortage and Public Health Emergency (PHE)-related PAS submissions that do not require Pre-Approval Inspection (PAI) or Pre-License Inspection (PLI) activities, an 8-Month Extended Track goal date for PAS submissions where the Office of Pharmaceutical Quality (OPQ) requests foreign PAI/PLI activities, and a 4-Month Standard Track goal date for all other manufacturing changes. Industry countered with the idea for a 2, 4, 6-month goal date model. Industry explained that with this model if the PAS submission did not need an inspection, it would receive a 2-month goal date. If the submission required a foreign inspection, it would receive a 6-month goal date. Any other submission outside of those parameters would receive a

4-month goal date. FDA noted that implementing a 2-month goal date for certain PAS submissions was not a resource neutral proposal. FDA discussed the variation and application complexities that are received by the Agency regardless of whether an inspection is required and emphasized that it would generally be very challenging to review PAS submissions in two months given the number and complexity of PAS received by FDA. FDA agreed to take Industry's 2 -4 - 6-month counter proposal back to their subject matter experts for discussion and provide feedback in the next meeting.

Facility Lifecycle

FDA reviewed draft commitment letter language for each element of the Facility Lifecycle Proposal. Industry expressed concerns with the changes outlined to the statutory text. Industry also questioned the potential value of early facility engagement with the Agency. Specifically, Industry questioned whether a company would still receive an inspection if that company agreed to participate in any of the elements of the Facility Lifecycle proposal and effectively implemented the advice received at these engagements. Additionally, Industry noted risks with the proposal that the Agency could trigger a for-cause inspection if the Agency were to witness an issue that was outside of the scope of the FDA's pre-engagement activities and affecting existing products. The FDA clarified that while these pre-engagement activities are intended to be targeted in scope and support facility readiness, the Agency will not ignore any risks to public health when information becomes available to FDA to inform such risks. Industry highlighted the need to see the effectiveness and value of this proposal demonstrated quantitatively. Industry questioned whether the FDA could accept a Type V Drug Master File (DMF) in advance of an application and the FDA agreed to take that back to their subject matter experts. Industry also questioned if the FDA had considered the Facility Lifecycle proposal as a pilot. The Agency noted being open to a pilot, developing the proposal at a smaller scale, or having a phased approach for implementation. Industry acknowledged the Agency's suggestions for measuring and reporting findings but reiterated a need for assurance of a quantifiable result. Industry also expressed concerns for companies who may not utilize the components of this proposal or own their own facilities would still be committed to paying for it. In response, FDA stated that all elements of the Facility Lifecycle Proposal will be available to all companies, and it will be the companies' responsibility to utilize these elements based on their development and business strategy.

Next Steps

The goals for the next meeting on December 9, 2025, include FDA sharing feedback on Industry's proposed 2-4-6-month goal date model for the PAS Timeline proposal, reviewing Industry's suggestions for Commitment Letter language for the Facility Lifecycle proposal, clarifying if a Type V DMF can be accepted in advance of an application, and discussing the FDA cost estimate for the Facility Lifecycle proposal.