



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

December 16, 2025 | 10:30am -12:30pm

Virtual - Microsoft Teams

MEETING PURPOSE

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

PARTICIPANTS

FDA

Larry Lee	CDER
KaLonna Maull	CDER
Don Henry	CDER
Mahesh Ramanadham	CDER
Lisa Harlan	CDER
Emily Ewing	CDER
Ivy Sweeney	CDER
Denise Gavin	CBER
Rebecca Frey-Cooper	CDER
Christine Hunt	OCC
Kate Greenwood	OCC
Andrew Kish	CDER

Industry

Carl Garner	PhRMA (Eli Lilly)
Ryan Kaat	PhRMA
Drew Sansone	BIO (Alkermes)
Kelly Goldberg	PhRMA
Derek Scholes	BIO

MEETING SUMMARY

The meeting discussion focused on FDA's feedback to draft commitment letter language and clarifying questions pertaining to existing resource options for FDA's Facility Lifecycle proposal.

Facility Lifecycle

FDA acknowledged receipt of Industry's draft commitment letter language and emphasized that they cannot commit to rulemaking or binding FDA advice on facility assessment including inspections. The Agency noted they were not aware of a prior instance where FDA has committed to rulemaking as part of PDUFA. FDA highlighted they could commit to updating internal guidance and process documents that describe decision-making. These guidance and process

documents would outline how the information gathered during any element of the Facility Lifecycle proposal, specifically early engagement, would feed directly into inspection decisions and the subsequent scope and conduct of an inspection, should one be triggered. Industry explained that they were not proposing specific policies, but they would need more of a commitment to ensure the value of the FDA's proposal.

FDA explained that if Industry did not see enough value in the Facility Lifecycle proposal, then a discussion about resources associated with FDA's proposal was unnecessary. FDA noted Industry concerns with complete response (CR) rates and how the Agency provided data showing that the only increase was in Biologics License Applications (BLA) across a two-year period. Furthermore, when the Agency looked at the reasons for those CR rates, the CRs were predominantly due to facility issues that could not be resolved during the review cycle. The Agency saw the Facility Lifecycle proposal as a viable solution to those issues especially because of the early engagement opportunities (e.g., facility readiness assessment) that would allow industry to receive FDA feedback on their facility before application submission. Industry questioned what would stop the FDA from running a pilot on their own if they believed the Facility Lifecycle proposal creates value. The FDA noted that it would be challenging to use the existing staff and resources to cover additional work and engagement opportunities proposed by the Facility Lifecycle proposal, in addition to the complexities associated with the current statutory language and the specific work allowed under PDUFA.

Industry reiterated that as is, the FDA's current proposal did not have adequate assurance of value. Industry shared that there are some areas they do see value in and would like to make some alternate proposals. Specifically, Industry noted offering alternate proposals related to pre-submission meetings, post-inspection meetings and other elements of their original proposal shared with the Agency. FDA highlighted that while there is value in conversation, post-inspection meetings will not address the root cause of the facility-related problems or provide enough time to solve them to prevent a CR. Industry countered that post-inspection meetings do increase transparency for sponsors. Industry agreed to provide alternate proposals, and FDA agreed to review those alternate proposals.

Next Steps

The goal for the next meeting on January 6, 2025, is for FDA to share feedback regarding Industry's alternate proposals related to the Facility Lifecycle.