



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

December 9, 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

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|-------------------|------|
| Larry Lee | CDER |
| KaLonna Maull | CDER |
| Don Henry | CDER |
| Mahesh Ramanadham | CDER |
| Lisa Harlan | CDER |
| Emily Ewing | CDER |
| Ivy Sweeney | CDER |
| Denise Gavin | CBER |
| Christine Hunt | OGC |

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 Industry and FDA's responses to clarifying questions pertaining to FDA's Facility Lifecycle and Manufacturing Prior Approval Supplement (PAS) Timeline proposals.

Facility Lifecycle

FDA acknowledged Industry's request for more quantitative metrics related to the Facility Lifecycle proposal. In response, the Agency reviewed a summary table of potential commitments and the perceived quantitative and qualitative impact each commitment could provide. FDA emphasized that while they support the goal of increased regulatory transparency and clarity, developing commitment language that includes assessment or regulatory decisions would not be appropriate for inclusion in the commitment letter. Industry questioned whether a written response from the FDA to a company that volunteers to utilize an element from the Facility

Lifecycle proposal was binding. The FDA explained that the engagement and discussions between the company and the Agency during the pre-submission stage become valuable information that will be leveraged in streamlining the facility evaluation and decision making for drug applications. FDA clarified that this process is no different than the regulatory feedback that industry receives from the FDA during the investigational new drug (IND) process for CMC development. Industry shared draft language for a commitment within the Facility Lifecycle proposal to provide for guidance and rulemaking addressing how engagement under the Facility Lifecycle proposal would inform FDA's risk-based approach to oversight and when advice provided at these engagements would be treated as binding, with certain exceptions. Industry shared this draft language, and the Agency agreed to provide feedback.

Next, FDA reviewed an estimate of the resources needed (in terms of full-time equivalents (FTEs) to implement each element of the FDA's Facility Lifecycle proposal. Industry questioned whether FDA could fund the Facility Lifecycle proposal using existing resources. The Agency emphasized that this proposal could not be implemented with existing FTEs. The Agency also indicated that it may be helpful to implement the Facility Lifecycle proposal at a smaller scale and then gradually scale up to the full program, so the FDA and Industry can work together to ensure that the intended outcomes are achieved. The FDA asked Industry what elements of the proposal Industry felt were most valuable.

Industry also indicated concerns that changing statutory language to enable Facility Lifecycle activities could have unintended consequences. As a follow up to a previous action item, FDA confirmed that a Type V Drug Master File (DMF) can be accepted in advance of an application.

Prior Approval Supplement (PAS) Timelines

Industry explained that after sharing the Agency's feedback with their constituents, there was no interest in changing the current PAS timeline. FDA emphasized the increasing difficulty in meeting the current 4-month clock, specifically for foreign inspections. FDA and Industry agreed to discontinue discussion of the PAS Timelines proposal.

Next Steps

The goals for the next meeting on December 16, 2025, include FDA sharing feedback on Industry's proposed language for a commitment to rulemaking, FDA sharing feedback on Industry's questions related to executing the Facility Lifecycle proposal with existing resources, and Industry sharing feedback on their prioritization of the Facility Lifecycle proposal elements.