



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

February 17, 2026 | 10:30am -12:30pm

Virtual Format

MEETING PURPOSE

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

PARTICIPANTS

FDA

Sau (Larry) Lee	CDER
Don Henry	CDER
Mahesh Ramanadham	CDER
Lisa Harlan	CDER
Denise Gavin	CDER
Emily Ewing	CDER
Derek Smith	CDER

Industry

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

MEETING SUMMARY

Industry shared their perspective on retaining the “Enhancing Inspection Communication” language from PDUFA VII in the PDUFA VIII commitment letter. Industry also shared feedback on FDA’s proposed meeting mechanics for the proposed pre-submission facility and post inspection meetings, and FDA and Industry discussed the feedback. FDA agreed to begin drafting commitment letter language.

Revisit Inspections Communications Language

Industry stated that they strongly prefer to maintain the 60-day notification language for inspections included in the PDUFA VII commitment letter. Industry indicated that the 60-day notification, when provided, helps sponsors plan their manufacturing schedules. FDA indicated that it would consider how the 60-day notification language fits with the proposed facility lifecycle approach and provide perspectives at a future meeting.

Facility Lifecycle: Meeting Mechanics

Industry responded to the meeting mechanics for pre-submission facility meetings and post inspection meetings that FDA proposed at the February 10th CMC subgroup meeting.

Pre-Submission Facility Meeting

Industry expressed concern with FDA's proposal that facilities with a potential Official Action Indicated (pOAI) alert be ineligible for the pre-submission facility meeting. FDA shared that pOAI and OAI alerts indicate systemic issues that apply beyond the application and are not easily resolved. Industry noted that FDA acknowledged about thirty percent of pOAI are downgraded and the time required to finalize the classification could disqualify an eligible facility. FDA said they would consider this perspective.

Industry indicated that they generally agree with the topics proposed for pre-submission facility meetings and shared some suggestions for clarifying the language describing the topics.

Industry shared their interest in a third-party assessment of the utility of the proposed facility lifecycle meetings and suggested that a third party collect data about meeting utilization. FDA generally agreed with the third-party approach, and FDA added that the third party should also host a public meeting to discuss lessons learned and suggest improvements.

Post Inspection Meeting

Industry expressed similar concerns with FDA's proposal that facilities with a pOAI alert also be ineligible for the post inspection meeting. FDA shared that if the inspection findings only implicate the product relevant to the application, the facility would be eligible for the post inspection meeting; however, if the inspection findings also implicate other products, the facility would be ineligible for the post inspection meeting. FDA agreed to send Industry background materials that explain FDA's inspection procedures.

Industry also expressed concern with FDA's proposal that if a facility required a follow-up inspection, they would be ineligible for the post inspection meeting. Industry suggested that sponsors may be able to provide information that could reduce or remove the need for a follow-up inspection. FDA clarified that the intent is for facilities with severe issues that are unlikely to be resolved within the meeting and application timeframe to be out of scope for this meeting.

Industry reiterated their concerns that the timing of the post inspection meeting may consistently lead to a goal date extension. FDA and Industry discussed options for introducing flexibility in the meeting timelines that would limit the need for goal date extensions. FDA emphasized the importance of the pre-submission facility meeting in identifying and addressing issues, as opposed to attempting to address all issues via the post inspection meeting, and noted their intent to complete review by the originally assigned goal date when feasible.

Next Steps

The goal for the next meeting on February 19, 2026 is to discuss FDA's perspective on the inspections communication language. FDA will draft commitment letter language that incorporates Industry's feedback on meeting mechanics, for discussion beginning February 24th.