



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

February 10, 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
KaLonna Maull	CDER
Don Henry	CDER
Mahesh Ramanadham	CDER
Lisa Harlan	CDER
Denise Gavin	CDER
Francis Godwin	CDER
Emily Ewing	CDER
Danielle Villata	CDER
Rebecca Frey-Cooper	CDER

Industry

Carl Garner	PhRMA (Eli Lilly)
Ryan Kaat	PhRMA
Drew Sansone	BIO (Alkermes)
Kelly Goldberg	PhRMA
Steve Berman	BIO

MEETING SUMMARY

FDA presented proposed meeting mechanics (e.g., process, timelines) for the proposed pre-submission facility meeting and the post inspection meeting. FDA and Industry discussed questions posed by Industry, and Industry agreed to provide feedback on the proposed meeting mechanics at a later negotiations meeting.

Facility Lifecycle

Pre-Submission Facility Meeting Mechanics

FDA shared a proposed process and timelines for the proposed pre-submission facility meeting, modeled after FDA's existing Type B meetings. FDA confirmed that the pre-submission facility meeting would be between the applicant and FDA and would cover all the relevant facilities. FDA and Industry acknowledged challenges associated with applicants who use contract

manufacturers and multi-use facilities. FDA also confirmed that the pre-submission facility meeting would be available for all applicants to request. FDA and Industry agreed that a workshop at the midpoint of PDUFA VIII could be used to discuss utilization of the pre-submission facility meeting and identify any adjustments needed to improve the process. Industry emphasized the need for timelines that are predictable.

Post Inspection Meeting Mechanics

FDA shared a proposed process and timelines for the proposed post inspection meeting, and Industry asked clarifying questions. Industry also reiterated their concern that for inspections occurring near the end of the application cycle, a goal date extension may be required to hold the post inspection meeting. FDA noted the intent is to limit goal date extensions, to the extent possible. FDA and Industry discussed rare cases involving facilities with an Official Action Indicated (OAI) status. FDA emphasized that the post inspection meeting is not intended to resolve OAI issues within a review cycle, as (1) the resolution of these issues requires significant resources and time from both FDA and industry and (2) industry should address facilities with OAI or potential OAI issues proactively, before application submission. FDA also emphasized the importance of including both the applicant and facility representatives in the post inspection meeting and noted that a Letter of Authorization (LOA) between the applicant and facility should be part of the meeting package.

Next Steps

Industry agreed to review the meeting mechanics FDA proposed and provide feedback. The goal for the next meeting on February 12, 2026 is to begin discussing Industry's feedback on the proposed meeting mechanics and to discuss an approach to other parts of the CMC section of the PDUFA VII commitment letter.