Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

January 20, 2026 | 10:30am -12:30pm

Microsoft Teams

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
Emily Ewing	CDER	Derek Scholes	BIO
Ivy Sweeney	CDER		
Lisa Harlan	CDER		
Francis Godwin	CDER		
Rebecca Frey-Cooper	CDER		
Denise Gavin	CBER		
Danielle Villata	CDER		

MEETING SUMMARY

The meeting discussion focused on Industry sharing feedback on FDA's counter to Industry's counterproposal for Facility Lifecycle.

Facility Lifecycle

Industry acknowledged FDA's counter and expressed concern with the Agency proposing the ability to extend goal dates at the submission stage, when a facility does not meet readiness for inspection criteria, prior to completing an assessment of the application. Industry clarified that this concept was a non-starter for their stakeholders. Industry believes that if a facility in an application is not ready for inspection (e.g., an Official Action Indicated (OAI) facility) at the time of submission, this should generally be considered a Refuse to File (RTF) issue. Industry also

acknowledged FDA's pre-submission checklist concept and proposed expanding pre-submission interactions beyond a simple checklist to include briefing content that provides more context on facility readiness, supply chain complexity (i.e., facilities that support manufacturing of proposed products), and risk assessments to enable more meaningful pre-submission discussions. Industry agreed to provide details about their thoughts in writing. Industry noted that meetings should remain product-specific and tied to IND or application numbers to ensure the activities fall within the scope of the process for the review of human drug applications and avoid the potential need for statutory changes, with updates provided at submission on any changes made since the pre-submission meeting. Industry also proposed including facility readiness dates in submission packages to help FDA schedule inspections earlier and more efficiently. Industry emphasized its suggestion to remove the mandatory requirement of participation in the pre-submission engagement as a condition of participating in a post-inspection meeting, to allow for situations where issues arise during inspection that weren't anticipated.

Industry asked about the process for determining meeting attendance for the post-inspection meeting, noting their desire to request specific FDA participants (compliance, clinical, etc.) on a case-by-case basis to ensure appropriate expertise is present for different types of issues. Industry acknowledged FDA's concerns about the 15-day response timeline and suggested exploring alternative approaches that still provide adequate time for facility issue resolution.

Next Steps

The goals for the next meeting on January 27, 2026, include FDA sharing any non-starters related to the Facility Lifecycle proposal and counter proposals, additional feedback from their compliance team regarding meeting engagement, and their preliminary thoughts regarding post-inspection meeting rejection criteria. FDA and Industry will also discuss the availability for additional meeting times for the CMC sub-group with aims of reaching an agreement.