Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

January 6, 2026 | 10:30am -12:30pm

FDA White Oak Campus, Silver Spring

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		
Francis Godwin	CDER		
Denise Gavin	CBER		
Danielle Villata	CDER		

MEETING SUMMARY

The meeting discussion focused on reviewing the details of Industry's counterproposal to FDA's Facility Lifecycle proposal.

Facility Lifecycle

FDA acknowledged Industry's counterproposal and asked Industry to explain their counterproposal by outlining the problem they intended to solve and how each of the elements in their counterproposal aimed to solve that problem.

Industry proposed a timeline for communications associated with FDA Form 483 that is issued after a Pre-Approval Inspection (PAI). Industry's proposal included a 15-day response time after firms receive their 483 observations and a 15-day response time by the Agency upon receipt of a firm's response to 483 observations. In addition, Industry's proposal included an automatically

scheduled post-inspection meeting upon issuance of FDA Form 483. Industry acknowledged that there would be some instances that involve complex facility issues, and this element of their counterproposal would not enable sponsors and FDA to address these complex facility issues in first cycle in all cases but might in some. Industry highlighted their focus with this element of the proposal is a firm's ability to gain clarity on issues cited in FDA Form 483 that will lead to approvability issues and their ability to remediate those issues prior to an action from the Agency or down the road. Industry noted that even a modest reduction in Complete Response Letters (CRLs) would be significant and that, even in instances where there is no roadmap for timely remediation, clarity on the issues would still be helpful to the sponsor. FDA raised concerns around receiving a substantive 483 response from firms to address significant facility issues because there is not enough time for these issues to be resolved within the review cycle. The Agency also highlighted that every FDA Form 483 received by a firm does not result in a CR because the current process allows for minor issues to be resolved without a meeting. Industry and FDA agreed that outlining a way to put boundaries around post inspection meetings or a gatekeeping strategy was necessary to ensure that the PDUFA resources are used efficiently, and post inspection meetings are meaningful to resolve facility issues.

Next, Industry proposed a pre-submission meeting where the Agency and a sponsor would discuss the manufacturing site and potential inspection-related issues. Industry outlined that a sponsor would share information about the manufacturing sites with the goal of supporting FDA's risk-based approach. The Agency questioned Industry's perspective on the timing and expectation for discussion at the pre-submission meetings.

Industry also proposed CMC-related commitments regarding communication for inspection related issues during the review cycle. Industry proposed that the Day 74 letter include dates for interim milestone and known dates for any Good Manufacturing (GMP) or Good Clinical Practice (GCP) inspections that will occur during the review cycle. The FDA reiterated that the existing commitment in PDUFA VII related to communicating timing for pre-license inspections applies only when it is necessary to see manufacturing occurring.

Next Steps

The goals for the next meeting on January 13, 2026, include FDA sharing feedback on Industry's counterproposal.