



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

January 27, 2026 | 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

Larry Lee	CDER
KaLonna Maull	CDER
Don Henry	CDER
Mahesh Ramanadham	CDER
Ivy Sweeney	CDER
Denise Gavin	CDER
Francis Godwin	CDER
Rebecca Frey-Cooper	CDER
Lisa Harlan	CDER
Emily Ewing	CDER
Danielle Villata	CDER

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 post inspection meeting rejection criteria. FDA and Industry also discussed feedback from the Agency's compliance team and the subgroup's availability for an additional meeting each week.

Facility Lifecycle

The Agency discussed their compliance team's ability to participate in meetings and explained policy that restricts compliance from discussing a potential Official Action Indicated (OAI) before final OAI classification. Industry questioned how a sponsor would know if they were going down a path where the significant facility issues will lead to an OAI status. FDA agreed to follow up on compliance (i.e., CDER's Office of Compliance) transparency options.

Next, FDA reviewed elements from Industry's counterproposal that would be unacceptable for the Agency. FDA highlighted that the proposed 15-day timeline for FDA to review and provide feedback on Industry's responses to FDA Form 483 and hold a meeting within 3 days of FDA's response would be a non-starter. FDA emphasized the need for additional discussions around response times to ensure meaningful discussion of potential resolutions to facility issues identified in the Form 483.

FDA reiterated the importance of being proactive in addressing facility issues before application submissions to mitigate the rate of facility deficiencies that lead to Complete Response (CR) action. To that effect, FDA shared that post inspection meetings should focus on those instances where there is a reasonable likelihood that deficiencies can be corrected and not be held where deficiencies are unlikely to be corrected within the review cycle. To achieve this goal, FDA developed and shared proposed grant / deny criteria for post-inspection meetings that would be used to ensure meetings are held when appropriate. The Agency proposed that post inspection meetings would be denied for facilities already classified as Official Action Indicated (OAI), when basic readiness standards aren't met, or when Form 483 responses show inadequate Corrective and Preventative Action (CAPA) plans requiring reinspection. Included in the criteria was a subset of criteria representing draft thinking on "readiness for Pre-Approval Inspection/ Pre-License Inspection," that if FDA observed a facility failed to meet, would be another reason to deny a post inspection meeting. FDA shared that the inclusion of the failure to meet readiness for PAI / PLI as a denial criteria underscore the importance for facilities to assess and ensure readiness against clearly outlined standards, and take advantage of early interaction where needed, to ensure major facility issues that prevent approval are addressed before application submission. Industry acknowledged FDA's meeting denial criteria and noted high-level alignment with the need to outline specific meeting details. FDA agreed to create a diagram showing agreed-upon elements and outstanding items that need to be fleshed out.

FDA and Industry also discussed scheduling and agreed to add another negotiation meeting every week to ensure continued discussions and alignment on commitment language can be reached.

Next Steps

The goal for the next meeting on February 3, 2026 is to review the diagram and align on all agreed-upon elements, determine the details that still need to be discussed and start outlining each key process step associated with pre-submission and post inspection meetings and developing the language necessary for the commitment letter.