



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

March 3, 2026 | 1:00 pm – 3:00 pm

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To discuss the Incorporate Regulatory Science into Regulatory Decision-Making and Facilitate First Cycle Reviews proposals.

PARTICIPANTS

FDA

Mary Thanh Hai	CDER
Nana Adjeiwaa-Manu	CDER
Thamar Bailey	CDER
Marie Bradley	CDER
Meghana Chalasani	CDER
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Emily Ewing	CDER
Sonday Kelly	CDER
Andrew Kish	CDER
Phillip Kurs	CBER
Mark Levenson	CDER
Janet Maynard	CDER
Jennifer Mercier	CDER
Paul Phillips	CDER
Katie Rivers	CBER
John Scott	CBER
Issam Zineh	CDER

INDUSTRY

Mark Taisey	BIO (Amgen)
Donna Boyce	PhRMA (Pfizer)
Steve Berman	BIO
Carl Garner	PhRMA (Eli Lilly)
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Katrin Rupalla	PhRMA (J&J)
Drew Sansone	BIO (Alkermes)
Derek Scholes	BIO
Lucy Vereshchagina	PhRMA

MEETING SUMMARY

FDA responded to Industry’s Incorporate Regulatory Science into Regulatory Decision-Making revised action package checklist subproposal. FDA proposed minor revisions to the Facilitate First Cycle Reviews pivotal protocols draft commitment letter language. FDA and Industry discussed the approach to the third-party assessment.

Approach to Incorporate Regulatory Science into Regulatory Decision-Making Proposal

FDA responded to Industry's action package checklist proposal¹, which proposes that FDA create a new section in action packages designed to increase transparency and shared learning about regulatory science tools² that were considered during the drug's development and the regulatory review process. Industry's proposal suggested that FDA include a checklist of regulatory science tools in the new action package section. In the checklist, the sponsor would indicate the section of the application where the regulatory science tool was used, while FDA would indicate the section of the action package where the regulatory science tool was discussed, if applicable.

FDA presented its position that while the Agency is committed to advancing innovative regulatory science in drug development and regulatory decisions, it does not support Industry's proposal. FDA stated that, in the Agency's view, Industry's proposal is not substantially different from the original version presented on January 27th and does not address the stated problem Industry is trying to solve, which is to increase transparency and shared learning about the use of regulatory science tools in the regulatory review process. FDA expressed concerns with added staff burden and the level of effort to move discussions from the Investigational New Drug (IND) stage, where many regulatory science tools are important in drug development, to the New Drug Application (NDA) or Biologics License Application (BLA) stage. FDA stated it was concerned that Industry's proposal did not appear to require sponsors to complete the checklist but noted that it was open to a broader conversation outside of PDUFA negotiations to discuss shared learnings regarding the use of regulatory science tools in drug development and regulatory decision-making.

Industry responded that it saw great benefit in the proposed action package checklist, stating that sponsors would complete the checklist in the application, and FDA will then complete the checklist in the action package. Industry also stated that if companies submit information in the application, but it is not addressed in the action package, then sponsors do not know whether regulatory science tools had been considered in the regulatory review process, which would be helpful for learnings that could be built into their clinical programs. Industry stated that an additional purpose of the checklist is to inform stakeholders - namely other sponsors and patient groups - that the regulatory science tools are being used. Industry also stated that sharing learnings could help address inconsistency across review divisions in acceptability of regulatory science tools.

FDA stated that Industry seems to be trying to address multiple perceived issues through the use of a checklist. After further discussion, FDA presented a counterproposal in lieu of the checklist,

¹ See the January 27th, February 10th and the February 19th meeting summaries for earlier versions of Industry's action package checklist proposal.

² These tools include novel endpoint development, Real-World Evidence (RWE), Drug Development Tools (DDT), including the use of biomarkers, Model-Informed Drug Development (MIDD), Complex Innovative Design (CID), Digital Health Technologies (DHTs), and Selective Safety Data Collection (SSDC).

citing concerns that there may be unintended consequences of Industry's proposal including biased estimates (e.g., underreporting) of regulatory science tool use. The counterproposal suggested that the Agency commit to holding a public meeting in which a broad set of stakeholders could discuss best practices in communicating the use of regulatory science tools in drug development and regulatory decision-making. Industry presented a narrowed proposal, including taking the proposed FDA narrative out, which Industry believed would further narrow down work required by FDA and have sponsors pre-populate the checklist without FDA commenting on whether the regulatory science tools in the checklist were considered in the regulatory review process. Industry's proposal would then have FDA include this sponsor-completed checklist in the action package, and Industry stated that this approach would increase transparency and address the issue identified earlier that it can be challenging for FDA to identify data leveraging regulatory science tools in the application. FDA and Industry both agreed to respond to one another's counterproposals and provide more details on their respective positions at the next meeting.

Approach to Facilitate First Cycle Reviews Proposal

FDA and Industry each presented proposed third-party assessment goals and objectives. FDA and Industry discussed the scope of the third-party assessment. Industry agreed to provide clarity on its proposed scope for the third-party assessment at a future meeting. FDA agreed to draft third-party assessment commitment letter language for Industry's consideration.

Approach to Draft Commitment Letter Language

In response to the February 26th meeting discussion, FDA proposed minor revisions to the pivotal protocols draft commitment letter language. FDA and Industry discussed the revisions, and Industry agreed to provide a final response to the draft commitment letter language in a future meeting.

Next Steps

The goals for the next meeting on March 5th will be to discuss the Rare Disease, Incorporate Regulatory Science into Regulatory Decision-Making, and Facilitate First Cycle Reviews proposals.