Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

December 16, 2025 | 1:00 pm–3:00 pm

Virtual Format

MEETING PURPOSE

To discuss Industry's response to FDA's Rare Disease proposal and continue discussing Industry's Enhancing Transparency and Consistency Related to Patient Experience Data (PED) proposal, Industry's Improve FDA-Sponsor Interactions proposal, and FDA's Meetings Management proposal.

PARTICIPANTS

FDA		INDUSTRY	
Mary Thanh Hai	CDER	Mark Taisey	BIO (Amgen)
Nana Adjeiwaa-Manu	CDER	Donna Boyce	PhRMA (Pfizer)
Thamar Bailey	CDER	Annetta Beauregard	BIO
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Kathleen Davies	CDER	Steve Berman	BIO
Emily Ewing	CDER	Kelly Goldberg	PhRMA
Sonday Kelly	CBER	Kristy Lupejkis	PhRMA
Andrew Kish	CDER	Alison Maloney	PhRMA (Bayer)
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Janet Maynard	CDER	Drew Sansone	BIO (Alkermes)
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Katie Rivers	CBER		
John Scott	CBER		
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MEETING SUMMARY

FDA and Industry discussed Industry's response to FDA's Rare Disease Proposal. FDA and Industry discussed FDA's revised response to Industry's PED proposal. FDA presented a revised version of its Meetings Management proposal.

Approach to Rare Disease Proposal

FDA responded to an additional data request from Industry inquiring about the functions the additional Full-Time Equivalents (FTEs) the Agency requested for PDUFA VIII would perform within CDER and CBER. FDA responded that the FTEs would be review staff supporting rare disease drug development, such as through completion of rare disease consultations. Industry asked clarifying questions to understand how FDA manages sponsor-submitted rare disease applications or meeting requests to the Agency. FDA responded that Industry meeting requests often ask for a rare disease staff member to attend and stated that the FTEs the Agency requested would be reviewers with rare disease product development expertise.

FDA asked for Industry's feedback on FDA's rare disease proposal. Industry presented the position that it continues to support the goals of the Rare Disease Endpoint Advancement (RDEA) pilot and intends to provide a counterproposal for RDEA in January 2026. Industry also expressed that it believes the Rare Disease Innovation Hub's (the Hub) training and workshops are important to understanding rare diseases and sharing learnings amongst FDA reviewers and Industry. Industry presented the position that FDA should consider ensuring that the Agency's proposed PDUFA VIII Hub commitments more directly translate to rare disease drug development advice and prescription drug review work. Industry emphasized that its position does not take away from the Hub's current and future work.

FDA asked for clarification on how the Hub can more directly translate into review work and regulatory decisions, stating that the Hub's workshops cover topics relevant to review work for rare diseases. FDA also stated that the Hub does not conduct review work, which remains within the review division's purview. Industry clarified that it does not envision the Hub conducting review work. Industry presented the position that it is not aligned on whether the Hub should be incorporated into PDUFA VIII commitments, stating that Industry needs to hear from FDA on the Hub's value in the review process. FDA and Industry agreed to continue discussing the rare disease proposal at a subsequent meeting.

Approach to Enhancing Transparency and Consistency Related to Patient Experience Data (PED) Proposal

The FDA and Industry reemphasized the value of PED and a shared commitment to PED.[1] FDA presented overarching perspectives on Industry's proposal in response to the December 11th discussion stating that patient input is critical throughout drug development, not all PED is necessary or appropriate to include in an FDA action package, and specifics of labeling include policy considerations. FDA also expressed that the Agency already documents PED in a review table with cross-references to relevant sections at the application review stage. FDA provided an

[1] See the December 11th meeting summary for details.

example of how FDA is documenting PED and stated that the Agency previously communicated issues it is currently seeing with PED submissions during the December 11th meeting. Industry acknowledged the FDA example as a comprehensive example of how PED was utilized, and requested FDA consistently document their use of PED in this manner. Industry provided a reference publication on FDA's limited/inconsistent use of the PED table[2]. FDA presented data on sponsor uptake in submitting PED in the correct area of approved NME submission between fiscal year 2019 and fiscal year 2024, stating that FDA issued an updated electronic Common Technical Document Technical Conformance Guide (eCTD TCG) in December 2019. The eCTD TCG directed sponsors to complete the Patient Experience Data table with its marketing application submission to facilitate FDA's review and determination on whether the PED was appropriate for regulatory decision for the particular submission. Despite this publicly available document, only a minority of marketing applications followed this recommendation. FDA presented a slide showing that in 2024, of 44 approved NMEs where FDA reviews identified PED in the submission, only 9 had the PED table completed by the sponsor alerting the FDA as to what type of PED were submitted. FDA also presented a slide showing the varied sections in a marketing application that PED was found including different subsections across Modules 1, 2, and 5. Based on FDA's analysis of PED submitted in this timeframe, the Agency stated that uptake had been limited in submitting PED as directed in the eCTD TCG.

FDA presented a list of Patient-Focused Drug Development guidances and other FDA efforts, such as workshops, trainings, and communications, to engage stakeholders in public venues to facilitate methods and use of PED in drug development. Industry emphasized interest in utilizing PED to inform labels. FDA presented the position that FDA and Industry have a shared responsibility to show the use of PED and that additional detail in the action package may not be the best venue to do so. FDA presented a slightly updated counterproposal to include case studies that highlight when PED data was used and when it was not used to inform regulatory decision making, in response to Industry's suggestion during the December 11th meeting. FDA reiterated its proposal to host a public meeting to discuss the case studies and facilitate broader dialogue about the collection, submission, and use of PED in drug development and regulatory review. FDA stated that the Agency believes this approach will advance PED considerations, rather than requiring additional documentation in the action package.

Following FDA's detailed presentation of the eCTD TCG and a sample PED table, Industry acknowledged that this was what they were asking for in their proposal and wanted to see where and how PED was used consistently and documented in the action package. FDA responded that there is currently a PED table in the reviews, which cross references to other sections of the review providing details on how PED was considered in regulatory decision. FDA stated that its understanding of Industry's proposal was that FDA's current approach needs further granularity on how all aspects of PED informed decision making, but FDA reiterated that not all PED is

[2] See https://doi.org/10.1007/s43441-025-00788-w for details.

informative to regulatory actions and would be an unnecessary burden for FDA to document all PED in the action package. Industry stated that it could address FDA's concerns by being clearer in its submissions, including completion of the PED table as instructed in the eCTD TCG.

Industry agreed with FDA's proposal to have case studies on the use of PED and a public meeting to discuss both positive and negative cases. Industry also stated that it would be helpful for the PDUFA VIII commitment letter to emphasize that sponsors should consistently complete the PED table in their submission. Industry asked if the Agency could share metrics for the number of time PED would be considered and rejected if sponsors flag in their submission that PED should be considered for regulatory decision making. FDA will take Industry's question into consideration. FDA agreed to review and agreed to draft commitment language and share it with Industry.

Approach to FDA Meetings Management and Industry Improve FDA-Sponsor Interactions Proposals

FDA presented its perspectives on Industry's Improve FDA-Sponsor Interactions proposal for FDA to revise and recommend its meeting timelines. FDA noted that User Fee commitment timelines with associated performance goals are established in the PDUFA commitment letter. Any other timelines (unless specified in statute) are aspirational. Resources are focused on achieving performance goals, which take priority over aspirational goals. FDA also stated that the Agency generally achieves meeting response and minutes timelines. However, FDA acknowledged scheduling meetings is a challenge. FDA stated that the Agency presented data and discussed the practical limitations such as challenges scheduling multiple reviewers, competing workload, and the growing imbalance of meetings to signatory ratio in previous meetings.[3]

FDA stated that it modified its Meetings Management proposal to address Industry and FDA's challenges. FDA's modified proposal includes moving Type B End-of-Phase meetings into their own category that reflects existing timelines. FDA revised its proposal to require meetings packages at the time of the meeting request to instead require meeting packages earlier than current timelines. FDA stated that meeting questions requiring input outside the core review team should be included in the meeting requests. FDA presented the proposal that if this information was not included at the time of request, the non-core reviewer might not attend the sponsor meeting and written answers would be sent after the meeting. FDA emphasized that meeting questions are what the Agency considers when scheduling meetings, noting that if it identifies needed reviewers late, it is challenging for them to be included in sponsor meetings or have their input incorporated. FDA noted that Type C Surrogate Endpoint meetings would continue to require the background package at the time of the request. To address Industry's concern that meeting scheduling would not happen on the last day of FDA's proposed window of days to schedule meetings, FDA proposed that Industry could choose to revert to PDUFA VII

[3] See the November 13th, November 18th, November 20th, and December 4th meeting summaries for details.

scheduling goals if FDA schedules more than half of meetings (excluding Type A) in the last 5 days of the scheduling window, effective the second year of PDUFA VIII.

FDA responded to Industry's Improve FDA-Sponsor Interactions proposal,[4] stating that FDA would consider providing the reason for converting a meeting to Written Response Only (WRO) for pre-IND, Type C, Type D, and Initial Targeted Engagement for Regulatory Advice on CBER/CDER Products (INTERACT) meetings. However, FDA presented the position that it does not agree with Industry's proposal to shift the final WRO decision to sponsors for these meeting types. FDA stated that doing so would quickly fill limited calendar space and result in delays that would not serve industry or FDA interests. FDA presented the position that it would consider including Type C, Type D, and INTERACT as eligible for Industry to submit a justification for a face-to-face meeting if FDA converts the meeting to WRO. FDA also presented the position that it does not agree with Industry's proposal for FDA to preschedule a teleconference for all WROs, with the sponsor canceling the pre-scheduled teleconference if the WRO is considered sufficient. In response to Industry's proposal that Type D meeting requests converted to a Type C meeting should include a detailed written rationale from the FDA to sponsors, FDA presented a review of data in response to Industry's initial data call for PDUFA negotiations, noting that 6% of Type D meetings have been converted to Type C meetings from 2018 to 2023.

Industry asked about whether FDA had considered incorporating the meeting minutes pilot the FDA Commissioner announced for FDA's Office of New Drugs[5] where sponsors, upon receiving FDA meeting minutes, can submit a clarification question via email for an FDA response within three business days. Industry also asked about how FDA's proposal that Industry could choose to revert to PDUFA VII scheduling goals if FDA schedules more than half of meetings (excluding Type A) in the last 5 days of the scheduling window would be reported to Congress. Industry asked whether they had understood correctly that comments from outside of the core review team would arrive after meeting minutes are issued if non-core review team member questions were not included in the background package.

FDA responded that the pilot Industry mentioned did not refer to a teleconference, and that FDA was proposing having a teleconference that is more consistent with what the PDUFA VII commitment letter states. FDA stated that it would need to see the current need before determining if the meeting minutes pilot would need to be incorporated. FDA stated that if meeting goals were to revert to those from PDUFA VII, FDA would report to Congress the percentage of meetings that met those. FDA emphasized that it would be important to determine if the Agency met the defined scheduling goals. FDA confirmed that Industry was correct that requiring comments from outside of the core review team would come after meeting minutes are

[4] See the November 4th meeting summary for details.

[5] See the Agency's press release, "FDA Pilots Faster Clarifications to Meeting Minutes" from November 19th, 2025, for details: https://www.fda.gov/news-events/press-announcements/fda-pilots-faster-clarifications-meeting-minutes.

issued if they were not in the meeting request. Industry agreed to review FDA's proposal in detail and respond at the next meeting.

Next Steps

The goals for the next meeting on December 18th will be to discuss progress in the premarket negotiations thus far, finalize the Complex Innovative Design commitment letter language, and discuss Industry's response to FDA's revised approach for Industry's Improve FDA-Sponsor Interactions and FDA's Meetings Management proposals.