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ADMINISTRATION**

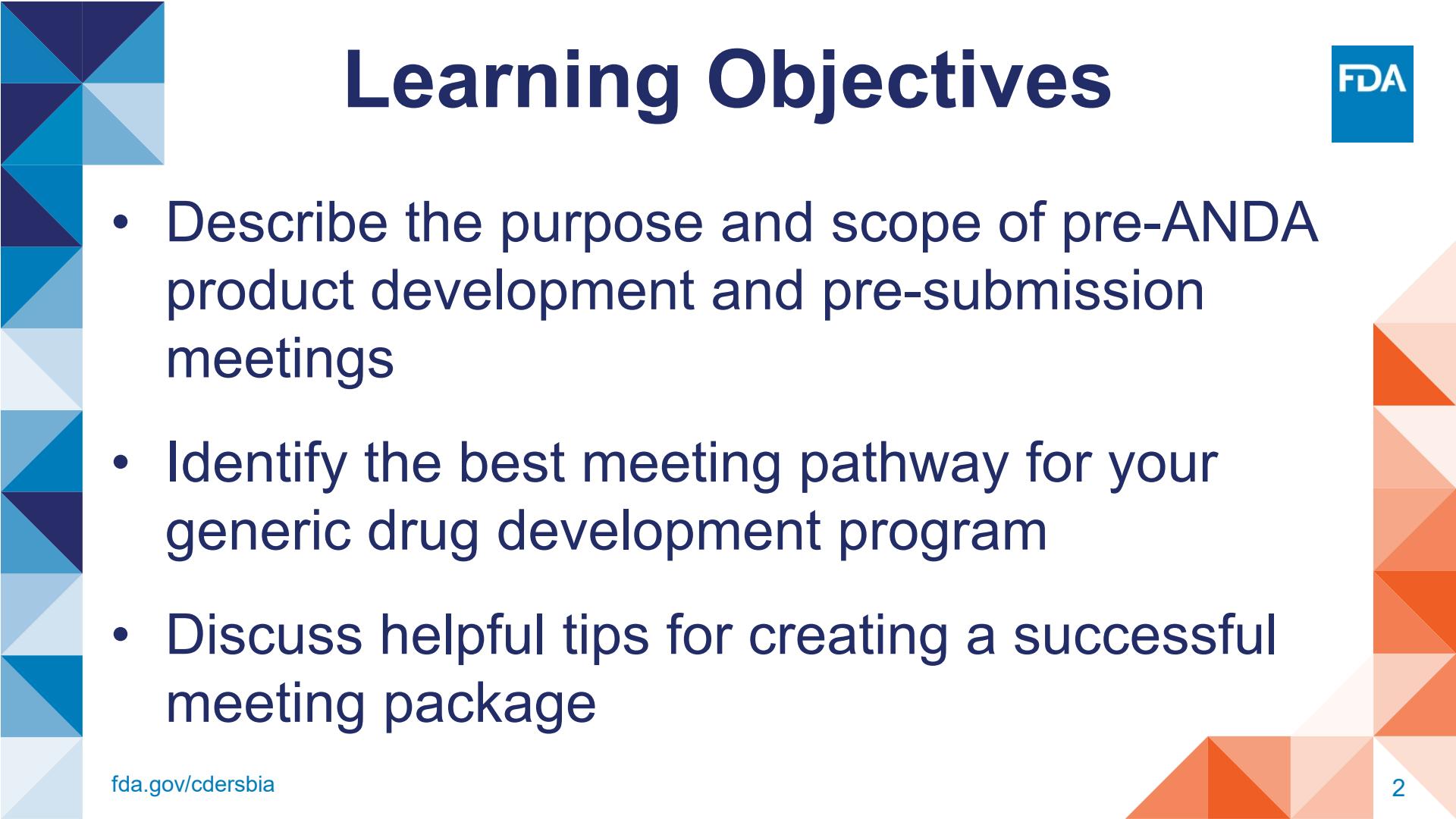
Pre-ANDA Meetings: Process and Best Practices

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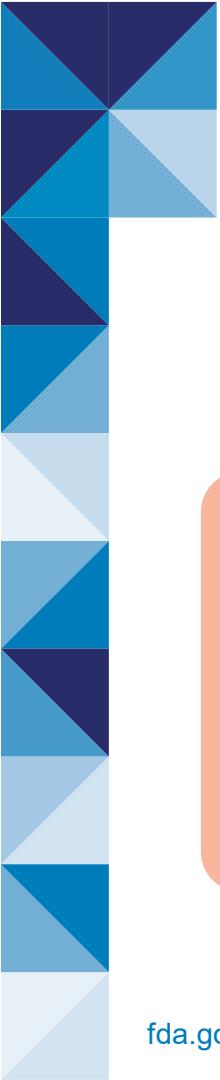
Generic Drug Forum 2025 – April 9, 2025



Learning Objectives



- Describe the purpose and scope of pre-ANDA product development and pre-submission meetings
- Identify the best meeting pathway for your generic drug development program
- Discuss helpful tips for creating a successful meeting package



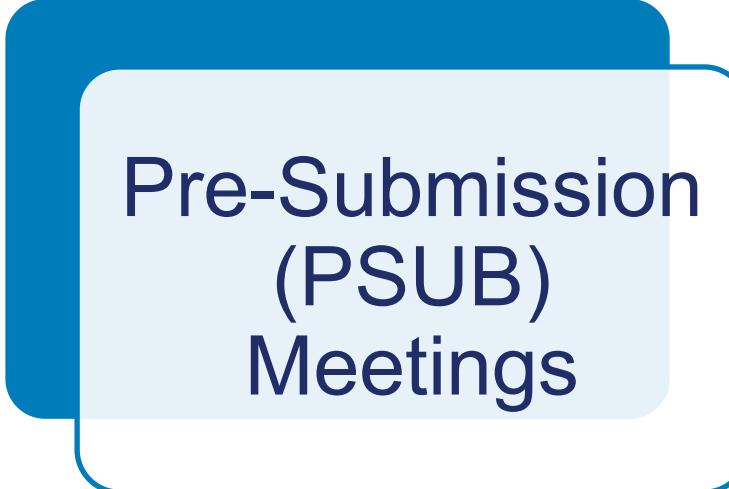
Pre-ANDA Scientific Meetings



Facilitate communications between FDA and prospective applicants related to complex products and/or complicated drug development questions



Product
Development
(PDEV)
Meetings



Pre-Submission
(PSUB)
Meetings

Pre-ANDA Scientific Meetings



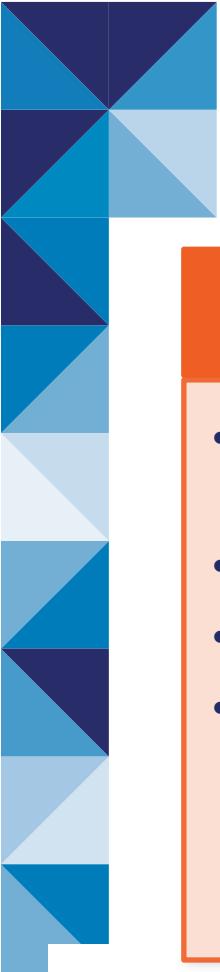
Additional Pre-ANDA Scientific Meetings available not covered under GDUFA III that may be more suitable for your program needs.

FDA-EMA
Parallel Scientific
Advice (PSA)
Program

Model-Integrated
Evidence (MIE)
Industry Meeting
Pilot

Refer to

- [FDA-EMA Parallel Scientific Advice Pilot Program for Complex Generic/Hybrid Products](#) Webpage
- [Expanding Generic Drug Access Through International Engagements](#) Webinar
- [Model-Integrated Evidence \(MIE\) Industry Meeting Pilot Between FDA and Generic Drug Applicants](#) Webpage
- [A Deep Dive: FDA's Model-Integrated Evidence \(MIE\) Industry Meeting Pilot Program for Generic Drugs](#) Webinar



CC or PDEV Meeting?



Controlled correspondence (CC)

- Single or small group of closely related questions
- Single discipline
- Outside scope of PDEV
- Response within 60 days (Level 1) or 120 days (Level 2)

PDEV Meeting

- Falls under will or may grant situation
- Multiple or multi-disciplinary questions
- New information, data, or questions not suitable for a CC
- Response within 120 days of PDEV being granted

Do not submit the same questions through a CC and PDEV meeting around a similar timeframe

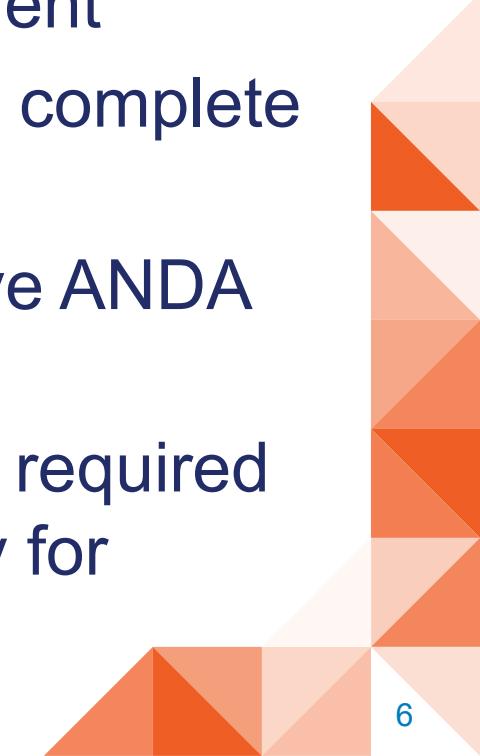


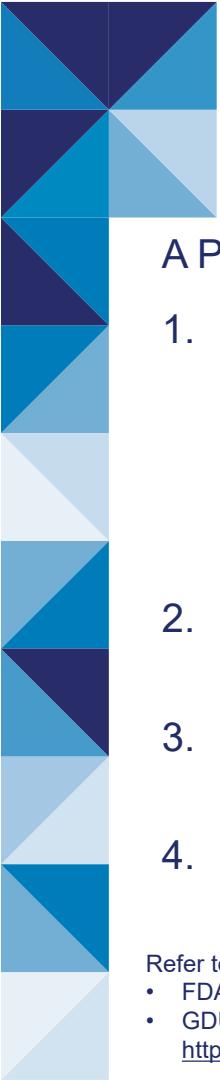


Pre-ANDA Program Goals



- Clarify regulatory expectations for prospective applicants early in product development
- Assist applicants in developing more complete and focused submissions
- Promote a more efficient and effective ANDA assessment process
- Reduce the number of review cycles required to obtain ANDA approval, particularly for **complex** products





PDEV Meeting Eligibility: Will Grant Situation

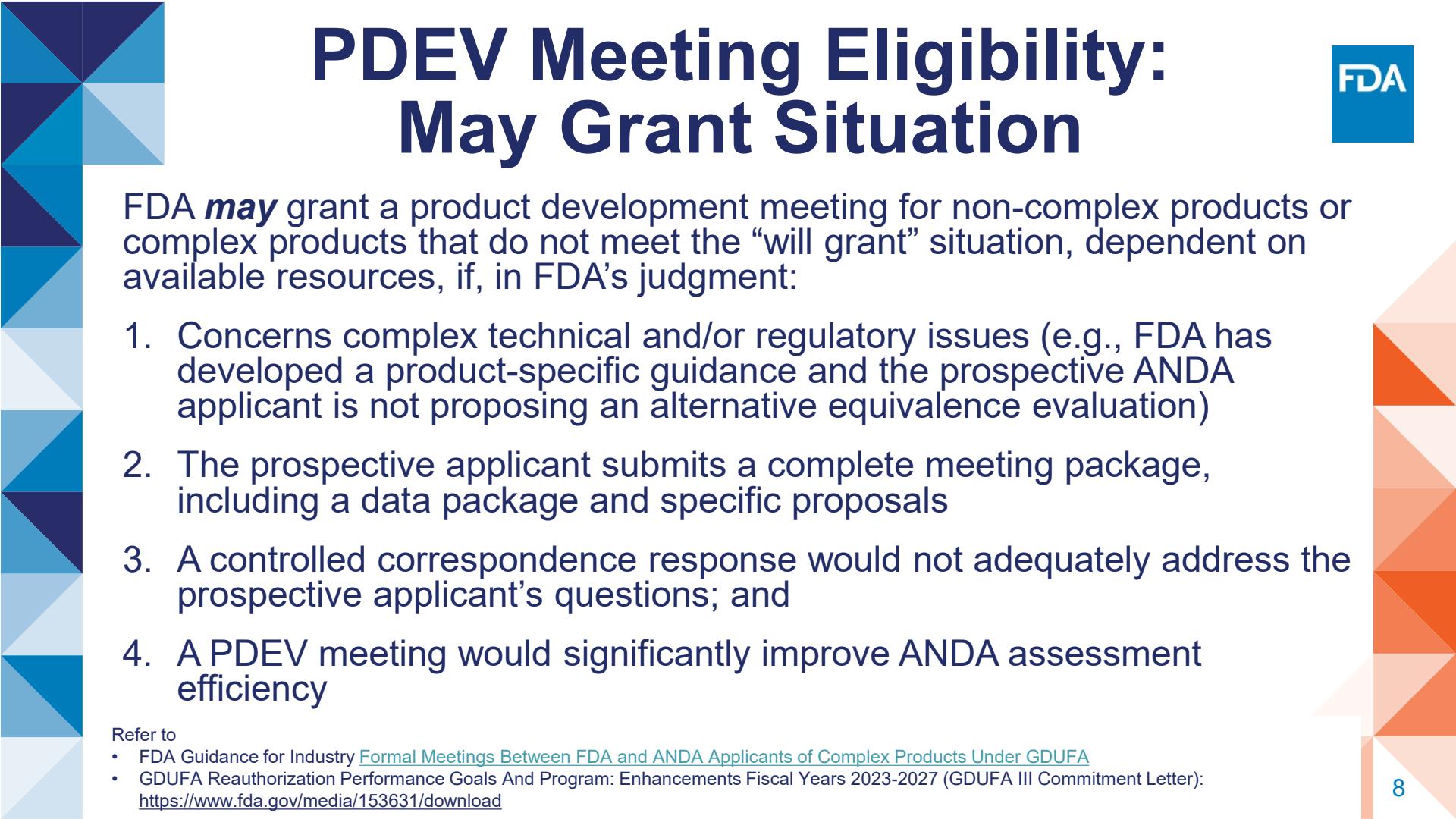


A PDEV meeting **will** be granted if in FDA's judgement:

1. The requested PDEV concerns:
 - a) Development of a Complex Generic Product for which FDA has not issued a product-specific guidance (PSG), or
 - b) An alternative equivalence evaluation, i.e., change in study type, such as in vitro to clinical for a Complex Generic Product for which FDA has issued a PSG
2. The prospective applicant submits a complete meeting package, including a data package and specific proposals
3. A controlled correspondence response would not adequately address the prospective applicant's questions
4. A PDEV meeting would significantly improve ANDA assessment efficiency (e.g., facilitate a generic development program via constructive feedback)

Refer to

- FDA Guidance for Industry [Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA](#)
- GDUFA Reauthorization Performance Goals And Program: Enhancements Fiscal Years 2023-2027 (GDUFA III Commitment Letter):
<https://www.fda.gov/media/153631/download>



PDEV Meeting Eligibility: May Grant Situation

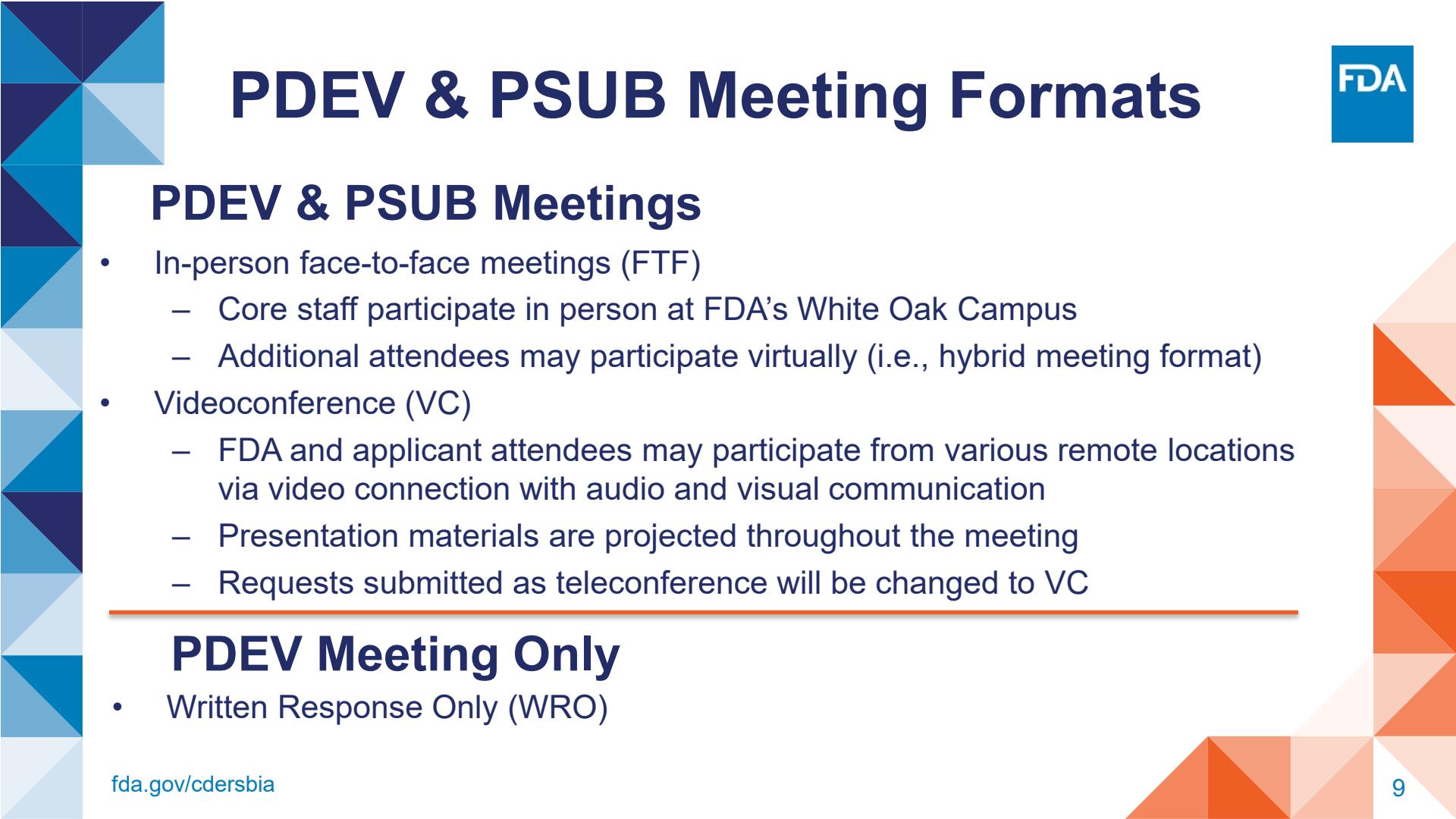


FDA **may** grant a product development meeting for non-complex products or complex products that do not meet the “will grant” situation, dependent on available resources, if, in FDA’s judgment:

1. Concerns complex technical and/or regulatory issues (e.g., FDA has developed a product-specific guidance and the prospective ANDA applicant is not proposing an alternative equivalence evaluation)
2. The prospective applicant submits a complete meeting package, including a data package and specific proposals
3. A controlled correspondence response would not adequately address the prospective applicant’s questions; and
4. A PDEV meeting would significantly improve ANDA assessment efficiency

Refer to

- FDA Guidance for Industry [Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA](#)
- GDUFA Reauthorization Performance Goals And Program: Enhancements Fiscal Years 2023-2027 (GDUFA III Commitment Letter): <https://www.fda.gov/media/153631/download>



PDEV & PSUB Meeting Formats



PDEV & PSUB Meetings

- In-person face-to-face meetings (FTF)
 - Core staff participate in person at FDA's White Oak Campus
 - Additional attendees may participate virtually (i.e., hybrid meeting format)
- Videoconference (VC)
 - FDA and applicant attendees may participate from various remote locations via video connection with audio and visual communication
 - Presentation materials are projected throughout the meeting
 - Requests submitted as teleconference will be changed to VC

PDEV Meeting Only

- Written Response Only (WRO)

PDEV Meeting Timeline

Grant/Deny Decision	w/in 14 days of FDA receipt date
Preliminary Written Comments	NLT 5 days before the meeting
Days to Conduct Meeting or Issue Written Response Only	w/in 120 days of FDA grant date
Meeting Length	60 minutes*
Meeting Minutes	w/in 30 days of meeting date

* FDA can at its discretion grant longer meetings when we determine it may be necessary

PDEV Meeting Request Package

FDA

DO



- Include specific and focused questions to allow timely discussion within 60 minutes
- List questions clearly and concisely and group by discipline for discussion

DO NOT



- Request a comprehensive assessment of study protocols without specific questions

Avoiding Denial – Helpful Tips

- Be specific and concise when asking your question by framing in a way that allows FDA to provide feedback (i.e., do not ask “Is this protocol acceptable?”)
- Avoid questions pertaining to assessment issues (i.e., do not ask “Is the proposed specification acceptable?”)
- Do not resubmit the same/similar question(s) already addressed in a CC (should be new question or data)
- Ensure your meeting package is complete and adequate information is provided to respond to questions (i.e., sufficient information on rationale/strategy for developing a specification and ask for feedback on the rationale/strategy)

Purpose of PSUB Meetings



Provide prospective applicant the opportunity to present **unique** or **novel** data or information that will be included in the ANDA submission, such as:

- Formulation
- Key studies
- Justifications
- Methods used in product development
- Interrelationship of the data and information in the ANDA

Your chance to orient identified FDA assessors in preparation for review of your upcoming ANDA submission and receive feedback on items or information that should be clarified

NOT meant for substantive assessment of summary data or full study reports and/or **NOT** an opportunity to determine whether the ANDA is acceptable for receipt

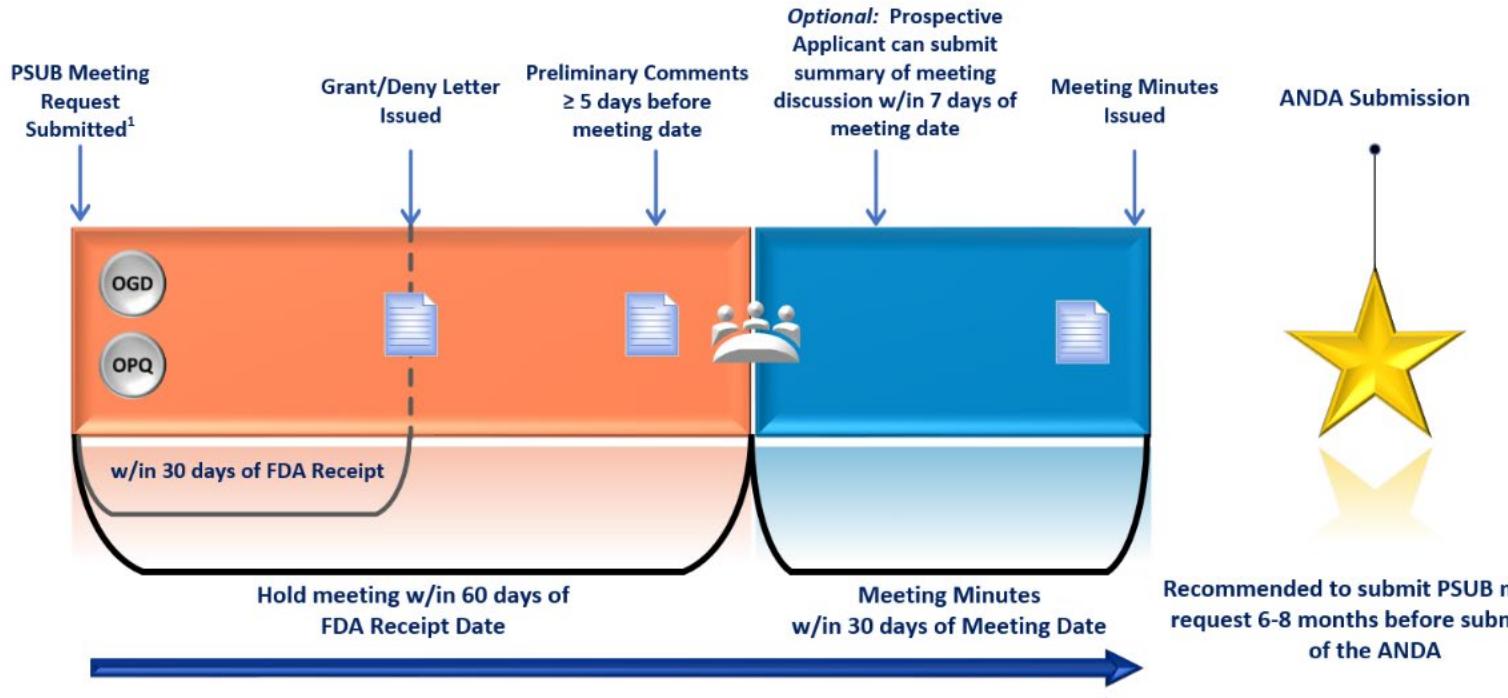
PSUB Meeting Eligibility



FDA will grant a PSUB Meeting:

- If prospective applicant was granted a prior product development (PDEV) meeting for the same complex generic product
- If FDA believes in its sole discretion that a PSUB meeting would improve ANDA assessment efficiency
 - Prospective ANDA applicants may request a PSUB meeting whether they had a PDEV meeting or not

PSUB Meeting Timeline



Recommended to submit PSUB meeting request 6-8 months before submission of the ANDA

PSUB Meeting Request Package



- Include information on regulatory history (e.g., prior PDEV meetings, CCs)
- Clearly identify main areas of focus for PSUB meeting (i.e., what do you want to give FDA assessors a “heads up” on)
- Consider submitting your meeting package in a draft presentation format

- Include technical questions¹
- Request written response only or teleconference meeting formats

¹ Questions should be submitted via controlled correspondence or product development meeting prior to PSUB meeting, as appropriate

Redesigned Pre-Submission Meetings in GDUFA III: Benefits for ANDA Submission and Approval: <https://www.fda.gov/drugs/news-events-human-drugs/redesigned-pre-submission-meetings-gdufa-iii-benefits-anda-submission-and-approval-05092024>

Avoiding Denial – Helpful Tips



- Do not include specific technical questions about your product development plan - send those in a controlled correspondence or PDEV meeting request
- Clearly articulate the unique issues of your development program, which will benefit by giving the FDA a preview into preparing for the ANDA assessment

Dispute of Meeting Minutes



- Prospective applicants requesting additional clarification of the meeting discussion should contact the assigned FDA point of contact (i.e., project manager) in writing within 10 calendar days of receipt of the official meeting minutes
 - If the meeting minutes are determined to accurately and sufficiently reflect the meeting discussion, the POC will convey this information to the prospective applicant
 - If, after discussions, FDA deems it necessary to change the official meeting minutes, the changes will be documented in an addendum to the official meetings

Resources



- GDUFA Reauthorization Performance Goals And Program: Enhancements Fiscal Years 2023-2027 (GDUFA III Commitment Letter): <https://www.fda.gov/media/153631/download>
- FDA Guidance for industry [Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA](#) (October 2022)
- MAPP 5220.8 (Rev 1): [Evaluating Requests for and Conducting Product Development and Pre-Submission Pre-ANDA Meetings](#) (October 2022)
- Infographic: [GDUFA III – Summary of Teleconferences and Meetings](#)
- MAPP 5240.10: [Classifying Approved New Drug Products and Drug-device Combination Products as Complex Products for Generic Drug Development Purposes](#)
- Guidance for industry [Controlled Correspondence Related to Generic Drug Development](#) (March 2024)
- Model-Integrated Evidence (MIE) Industry Meeting Program: <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/model-integrated-evidence-mie-industry-meeting-pilot-between-fda-and-generic-drug-applicants>
- SBIA Webinar: A Deep Dive: [FDA's Model-Integrated Evidence \(MIE\) Industry Meeting Pilot Program for Generic Drugs](#)
- FDA-EMA Parallel Scientific Advice Program: <https://www.fda.gov/drugs/news-events-human-drugs/fda-ema-parallel-scientific-advice-psa-program-03162022>
- SBIA Webinar: [Expanding Generic Drug Access Through International Engagements](#)
- GDUFA III Enhancement to the Pre-ANDA Program: <https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iii-enhancements-pre-anda-program>
- Redesigned Pre-Submission Meetings in GDUFA III: Benefits for ANDA Submission and Approval : <https://www.fda.gov/drugs/news-events-human-drugs/redesigned-pre-submission-meetings-gdufa-iii-benefits-anda-submission-and-approval-05092024>
- A Deep Dive: GDUFA III Scientific Meetings: <https://www.fda.gov/drugs/news-events-human-drugs/deep-dive-gdufa-iii-scientific-meetings-05152023>

Summary



- Review appropriate resources and guidances before submitting your meeting request
- PDEV - provide specific and concise questions and sufficient information on rationale/strategy for developing a specification
- PDEV - In-person FTF, VC or WRO meeting format
- PSUB - do not submit specific questions but highlight the unique or novel aspects you want to present
- PSUB - In-person FTF or VC only meeting format
- PSA and MIE are additional meetings that may be more suitable for your product development needs

