



Overview and Considerations of Pre-ANDA Scientific Meetings Under GDUFA III

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FDA Generic Drugs Forum (GDF) 2024 – April 10-11, 2024



Learning Objectives

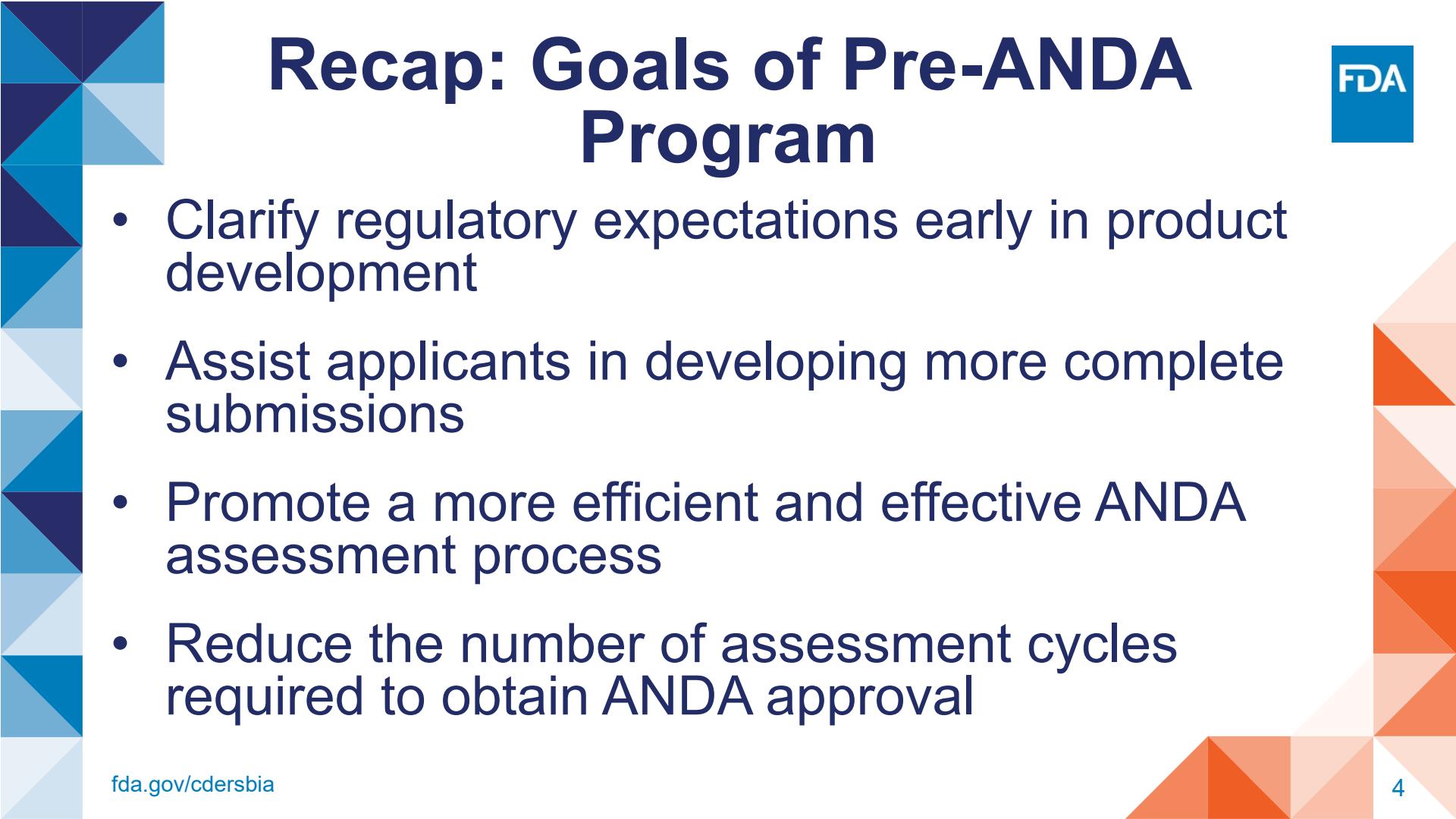


- Describe the purpose and scope of pre-ANDA product development and pre-submission meetings
- Acquire tips for meeting requests and package submissions
- Identify which pathway best works for your generic drug development program



Pre-ANDA Scientific Meetings

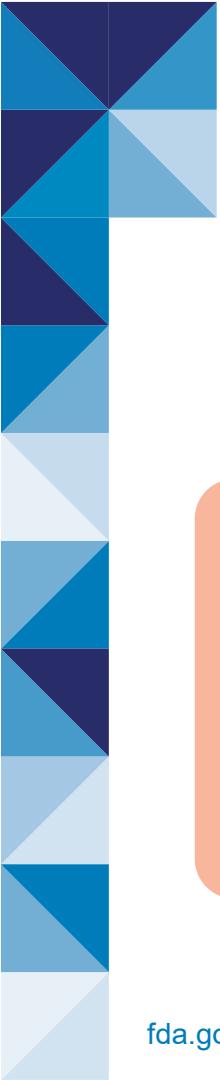
Background



Recap: Goals of Pre-ANDA Program



- Clarify regulatory expectations early in product development
- Assist applicants in developing more complete submissions
- Promote a more efficient and effective ANDA assessment process
- Reduce the number of assessment cycles required to obtain ANDA approval

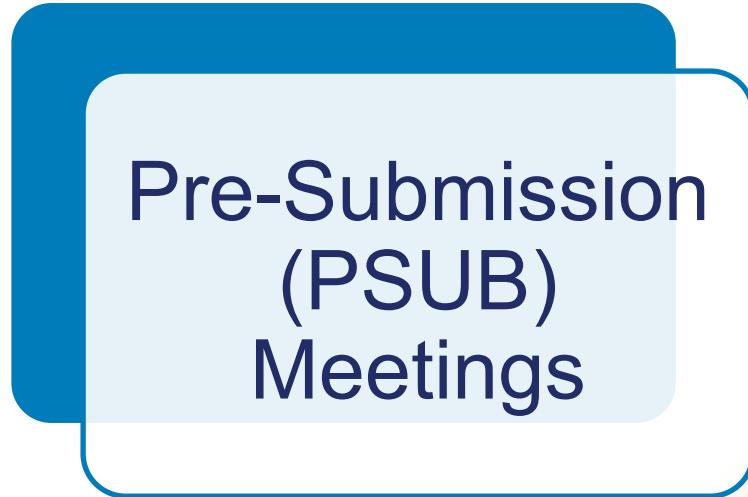


Pre-ANDA Scientific Meetings

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



Product
Development
(PDEV)
Meetings



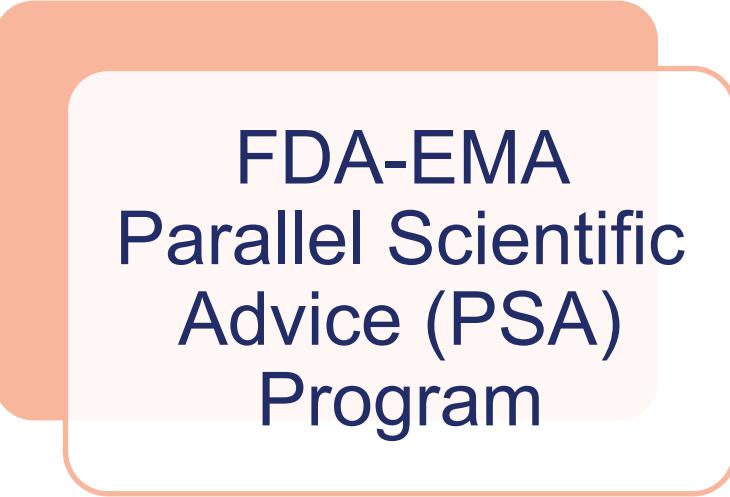
Pre-Submission
(PSUB)
Meetings



Pre-ANDA Scientific Meetings



Additional Pre-ANDA Scientific Meeting 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 Program Webpage](#)
- [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](#)



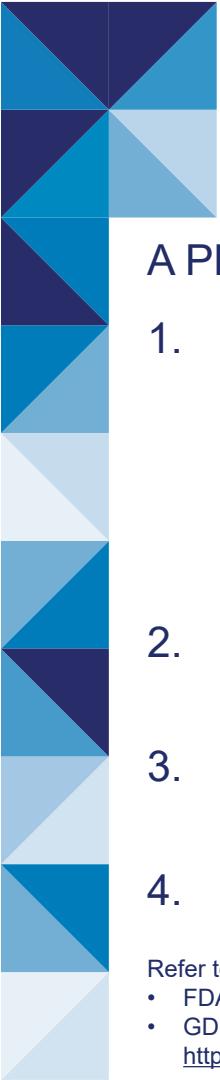


Product Development Meetings



- Forum for ***scientific exchange*** on specific issues or questions
 - Proposed study design
 - Alternative approach
 - Additional study expectations
- ***Targeted advice*** regarding ongoing ANDA development program





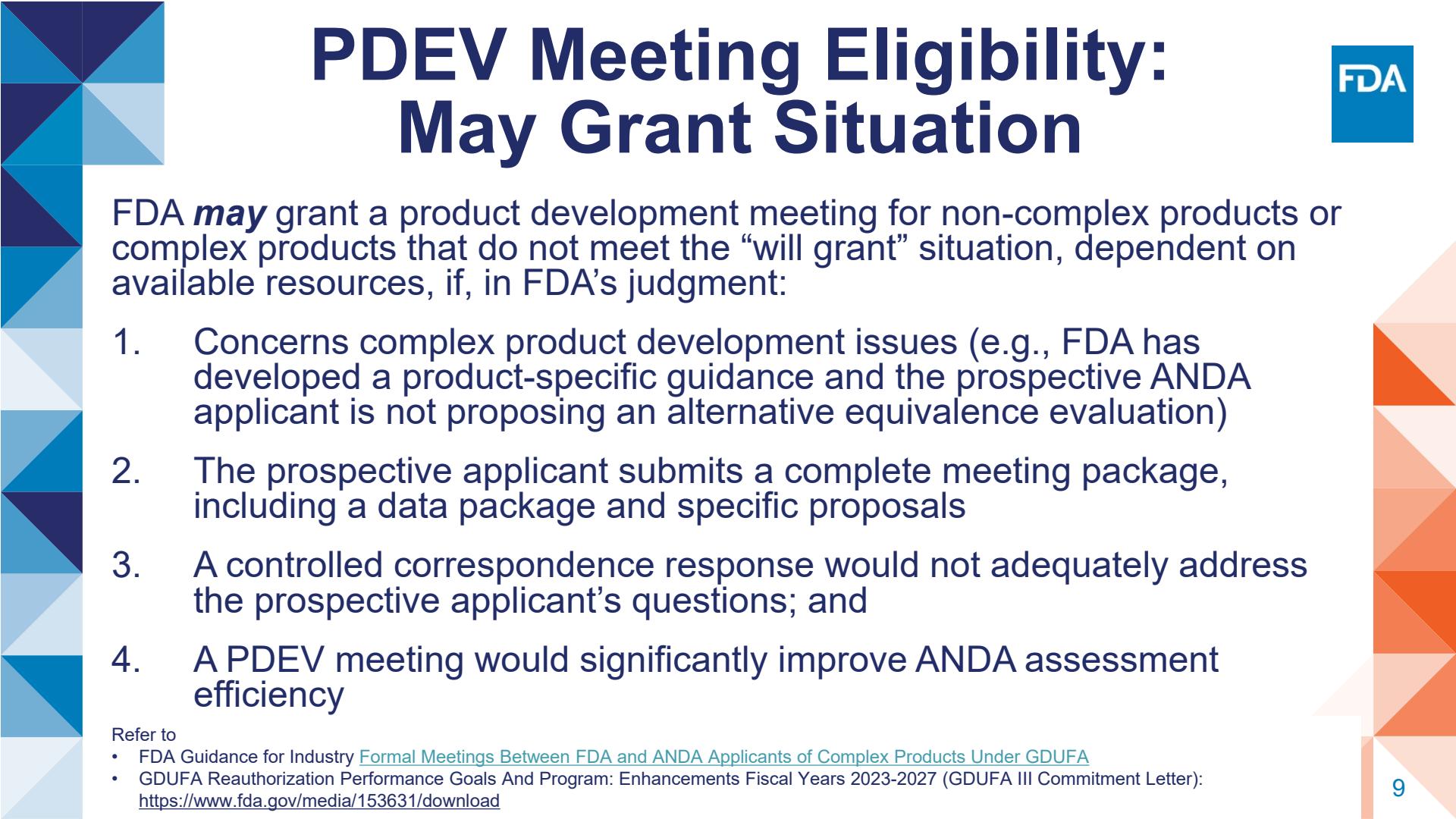
PDEV Meeting Eligibility: Will Grant Situation

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

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

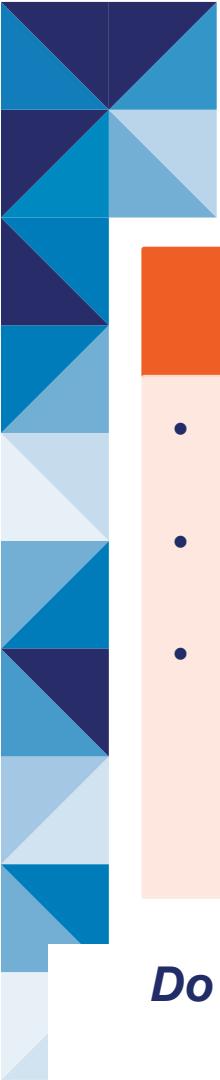


FDA **may** grant a product development meeting for non-complex products or complex products that do not meet the “will grant” situation, dependent on available resources, if, in FDA’s judgment:

1. Concerns complex product development 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](#)
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Controlled Correspondence or PDEV Meeting?



Controlled correspondence (CC)

- Single or small group of closely related questions
- Questions outside of PDEV scope
- 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

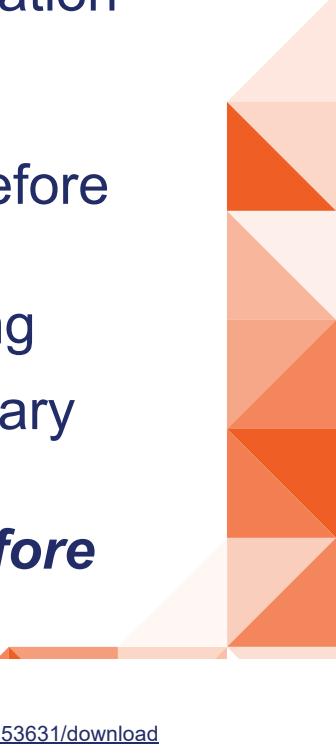
Do not submit the same questions through a CC and PDEV meeting around a similar time frame



Pre-Submission (PSUB) Meetings

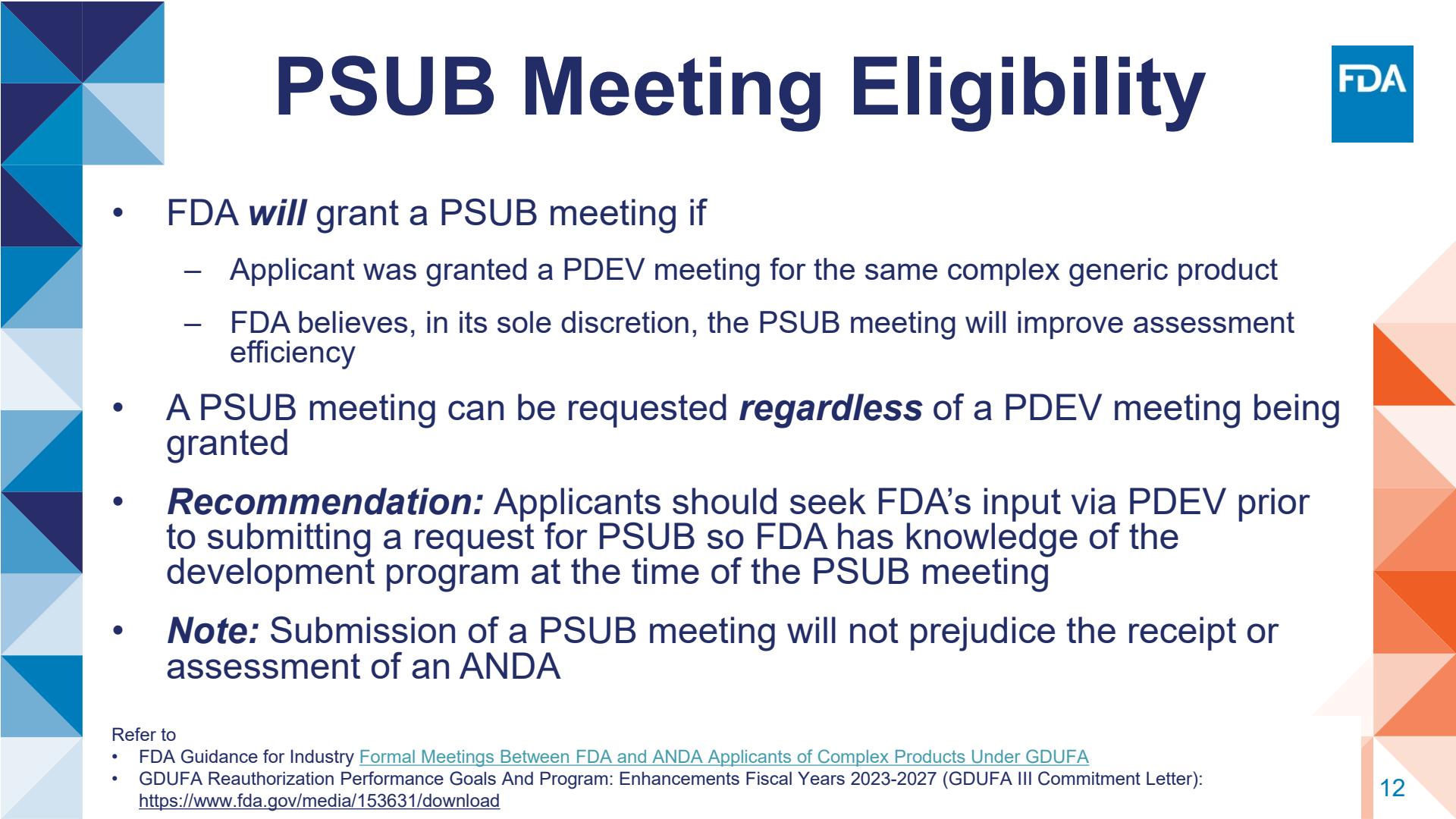


- Opportunity to ***present unique or novel*** data or information that will be included in ANDA submission
- Ability to receive ***FDA feedback*** on ANDA submission, including items or information that should be clarified before submission to improve chances of first cycle approval
- Redesigned in GDUFA III: Not a question-based meeting
- ***FDA will not*** provide substantive assessment of summary data or full study reports at the meeting
- Recommended Submission Timeframe: 6-8 months ***before*** anticipated ANDA submission



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>



PSUB Meeting Eligibility



- FDA **will** grant a PSUB meeting if
 - Applicant was granted a PDEV meeting for the same complex generic product
 - FDA believes, in its sole discretion, the PSUB meeting will improve assessment efficiency
- A PSUB meeting can be requested **regardless** of a PDEV meeting being granted
- **Recommendation:** Applicants should seek FDA's input via PDEV prior to submitting a request for PSUB so FDA has knowledge of the development program at the time of the PSUB meeting
- **Note:** Submission of a PSUB meeting will not prejudice the receipt or assessment of an ANDA

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 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 upgraded to VC

PDEV Meeting Only

- Written Response Only (WRO)
 - Meeting is granted beyond the scope of the commitment letter

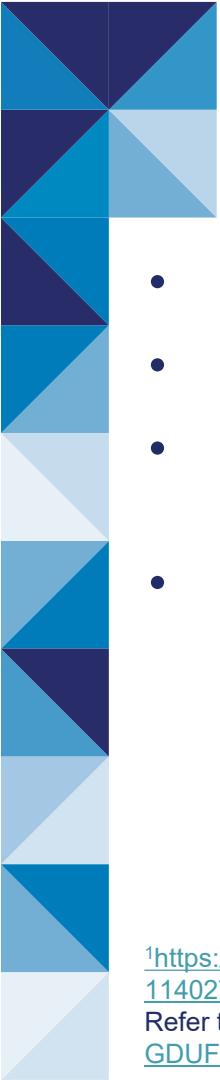
Challenge Question #1

As a prospective applicant, you wish to submit a pre-ANDA meeting to present unique or novel data or information in your upcoming ANDA submission. Which type of meeting request should you submit?

- a. Product Development (PDEV) meeting
- b. Pre-Submission (PSUB) meeting

Pre-ANDA Scientific Meetings

Package Contents & Tips



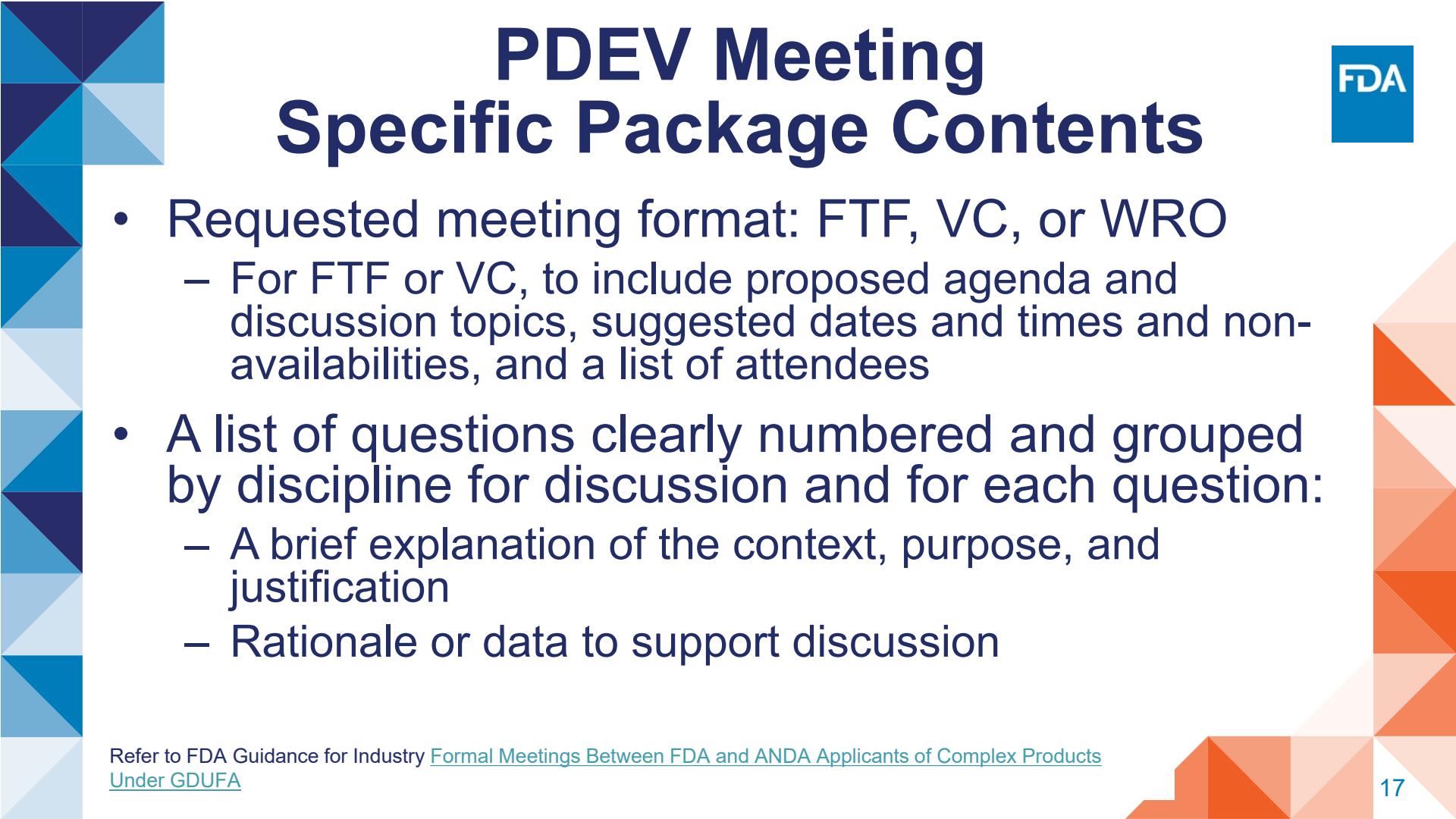
PDEV & PSUB Meeting Package Contents



- Pre-assigned ANDA number¹
- Established Name
- Reference listed drug and application number
- Brief statement on the purpose and objectives of meeting
 - To include a brief background of the issues underlying the agenda
- Chemical Structure
- Dosage form, route of administration, dosing regimen (frequency and duration)
- Proposed indications
- A brief statement indicating how the product meets criteria for a complex product
- A background section with a brief history on the development program, status of product development

¹<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm114027.htm>

Refer to FDA Guidance for Industry [Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA](#)



PDEV Meeting Specific Package Contents



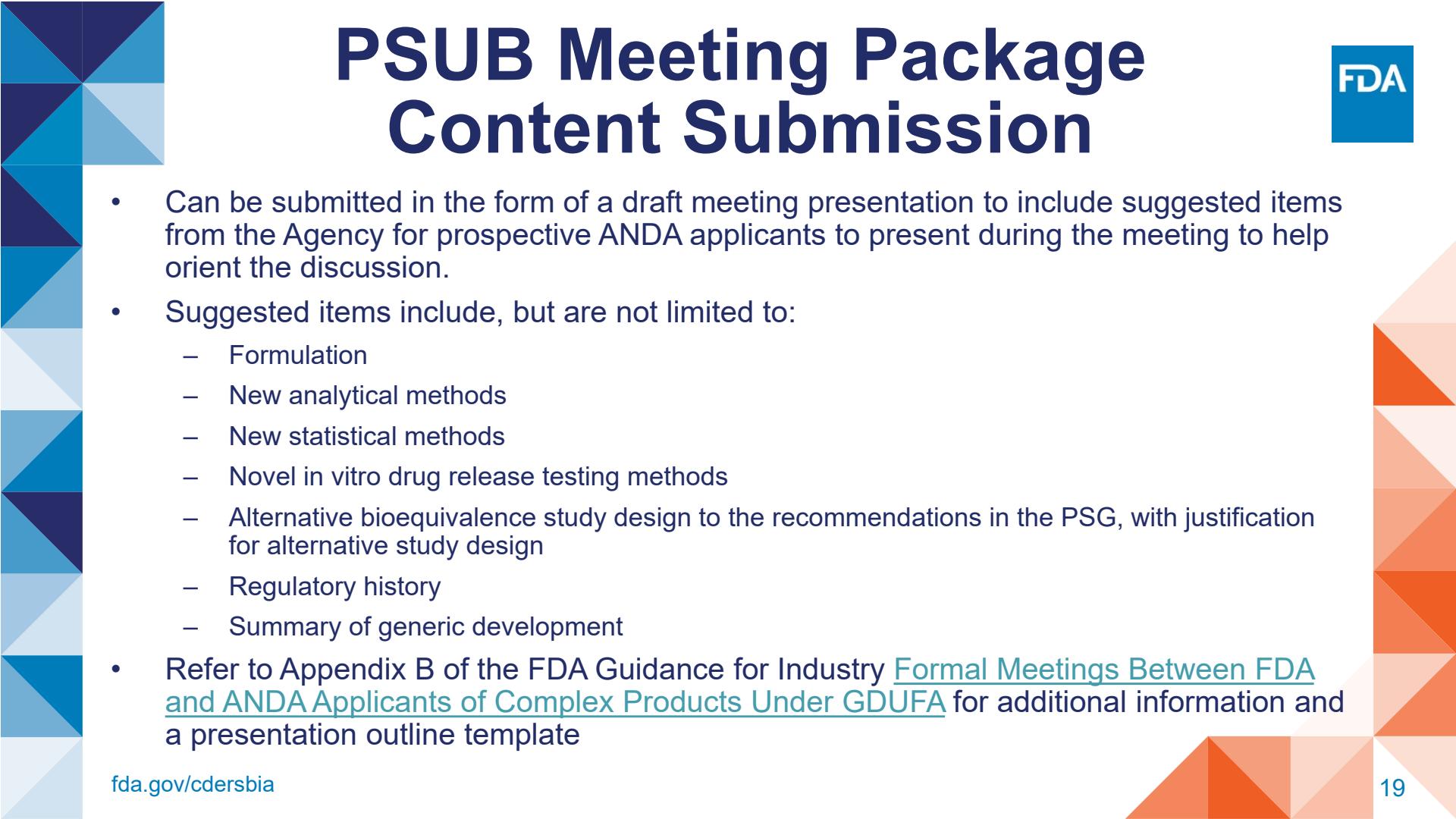
- Requested meeting format: FTF, VC, or WRO
 - For FTF or VC, to include proposed agenda and discussion topics, suggested dates and times and non-availabilities, and a list of attendees
- A list of questions clearly numbered and grouped by discipline for discussion and for each question:
 - A brief explanation of the context, purpose, and justification
 - Rationale or data to support discussion



PSUB Meeting Specific Package Contents



- Requested meeting format: FTF or VC, to include proposed agenda and discussion topics, suggested dates and times and non-availabilities, and a list of attendees
- **Key:** If a PDEV meeting was granted, include event IDs and summary of advice
 - If no previous PDEV meeting, provide an explanation why a PSUB meeting should be granted
- Estimated timeline for when the ANDA will be submitted for review
- **Key:** Unique or novel data or information that will be included in the ANDA submission
 - Formulations, key studies, justifications, and/or methods used in product development
 - Interrelationship of the data and information in ANDA



PSUB Meeting Package Content Submission



- Can be submitted in the form of a draft meeting presentation to include suggested items from the Agency for prospective ANDA applicants to present during the meeting to help orient the discussion.
- Suggested items include, but are not limited to:
 - Formulation
 - New analytical methods
 - New statistical methods
 - Novel in vitro drug release testing methods
 - Alternative bioequivalence study design to the recommendations in the PSG, with justification for alternative study design
 - Regulatory history
 - Summary of generic development
- Refer to Appendix B of the FDA Guidance for Industry [Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA](#) for additional information and a presentation outline template



More Tips



- Review all applicable guidances and standards before submissions
- For PDEV meetings
 - Ask specific questions, with sufficient justification and preliminary data (no data dumping) to support proposals
 - Avoid questions pertaining to assessment issues
- For PSUB meetings
 - Do not include specific questions about the development plan¹
 - Do not request a TC or WRO meeting format

Pre-ANDA Scientific Meetings

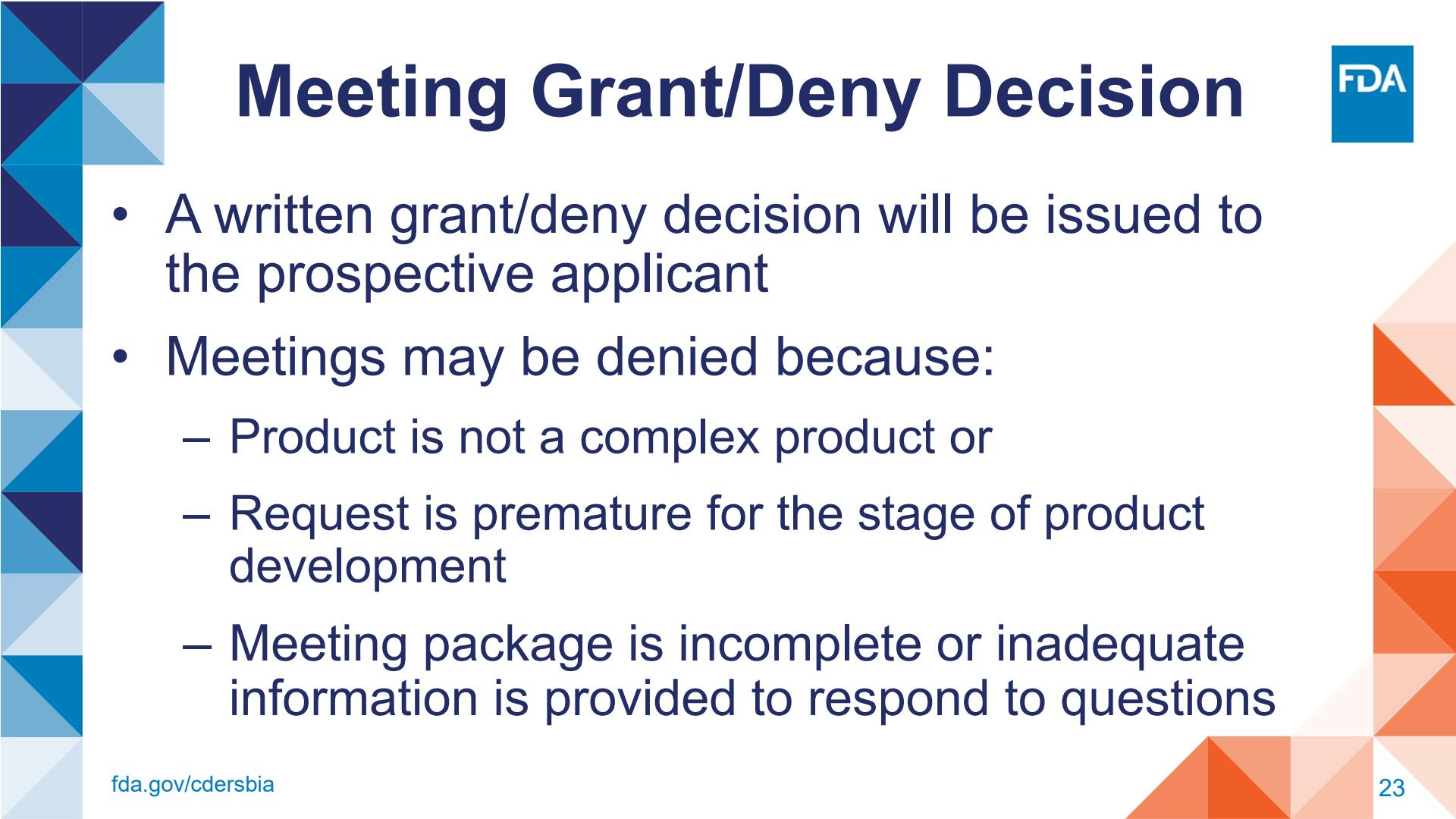
Meeting Timeline & Communication

Meeting Timeline



	PDEV Meeting	PSUB Meeting
Grant/Deny Decision	w/in 14 days of FDA receipt date	w/in 30 days of FDA receipt date
Days to Conduct the Meeting	w/in 120 days of FDA grant date	w/in 60 days of FDA receipt date
Preliminary Written Comments	NLT 5 days before the meeting	NLT 5 days before the meeting
Typical Meeting Length	60 minutes	60 minutes
Meeting Minutes	w/in 30 days of meeting date	w/in 30 days of meeting date

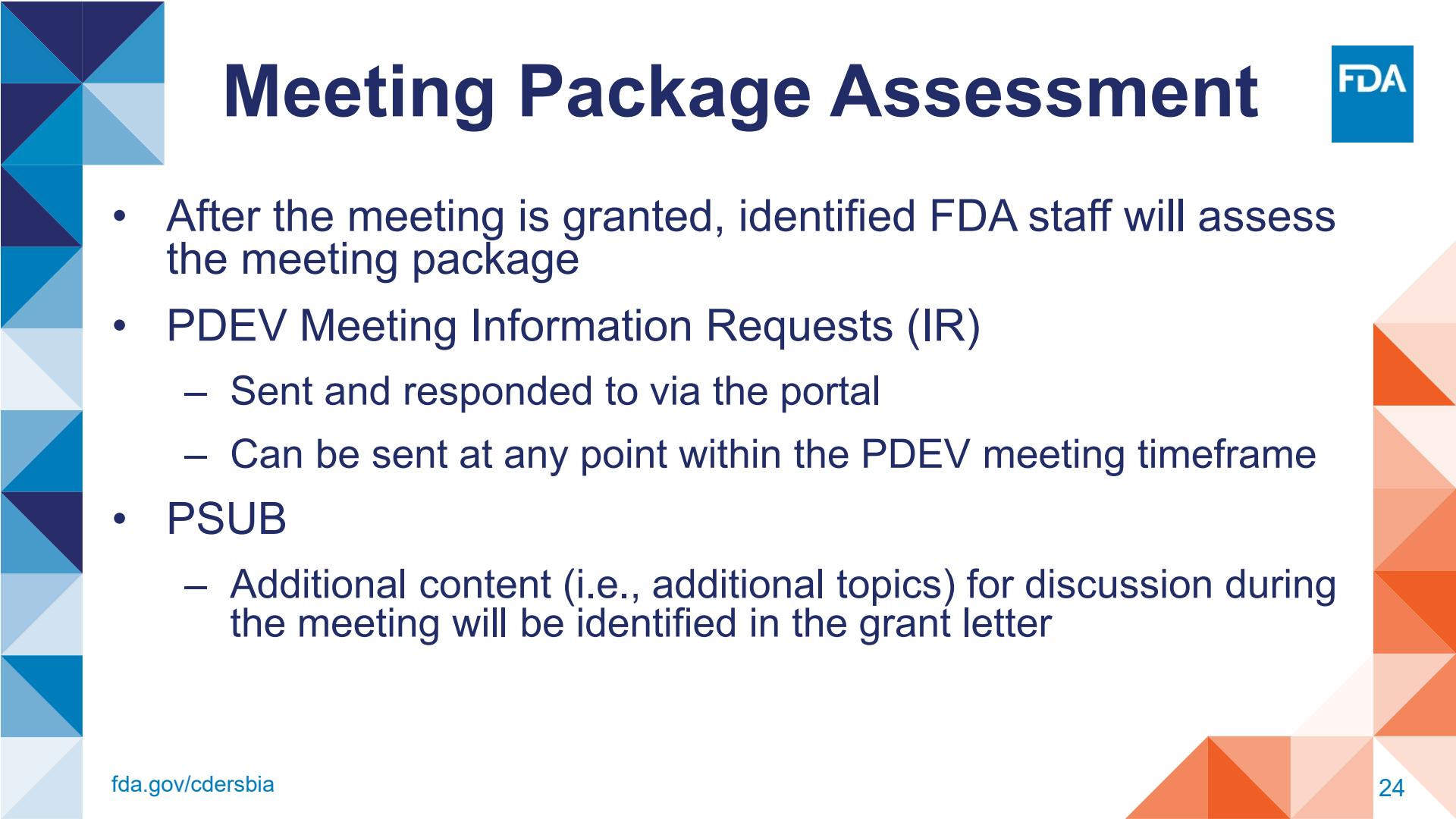
For PDEV granted as WRO, the written response will be issued within 120 days of the meeting grant date



Meeting Grant/Deny Decision



- A written grant/deny decision will be issued to the prospective applicant
- Meetings may be denied because:
 - Product is not a complex product or
 - Request is premature for the stage of product development
 - Meeting package is incomplete or inadequate information is provided to respond to questions



Meeting Package Assessment



- After the meeting is granted, identified FDA staff will assess the meeting package
- PDEV Meeting Information Requests (IR)
 - Sent and responded to via the portal
 - Can be sent at any point within the PDEV meeting timeframe
- PSUB
 - Additional content (i.e., additional topics) for discussion during the meeting will be identified in the grant letter

Preliminary Comments for FTF or VC



PDEV Meetings

- Preliminary response to questions submitted in meeting package
- Option to:
 1. Submit a revised agenda at least 48 hours before scheduled meeting
 2. Submit presentation materials at least 48 hours before scheduled meeting
 3. Cancel meeting if responses adequately address questions
 4. Change FTF meeting format to VC

PSUB Meetings

- Preliminary comments may request additional information to include in the presentation not previously identified in the grant letter or indicate no further comment
- Submitting updated presentation materials at least 48 hours before scheduled meeting to help focus meeting discussion
- ***Important:*** Preliminary comments from FDA should not result in cancellation of PSUB meeting



Day of Meeting Meeting Conduct

PDEV Meetings

- Meeting will follow applicant's updated agenda
- Discussion should focus on clarification of Agency's preliminary comments
 - FDA **will not** address or comment on any new data or questions not presented in the original meeting package

PSUB Meetings

- Meeting will follow final presentation submitted
- FDA will provide feedback on items or information that should be clarified before ANDA submission to improve chances of first cycle approval



Post-Meeting Communication



- Following a FTF or VC meeting, the prospective applicant can submit a meeting summary within 7 calendar days
- FDA will issue meeting minutes within 30 calendar days after the meeting

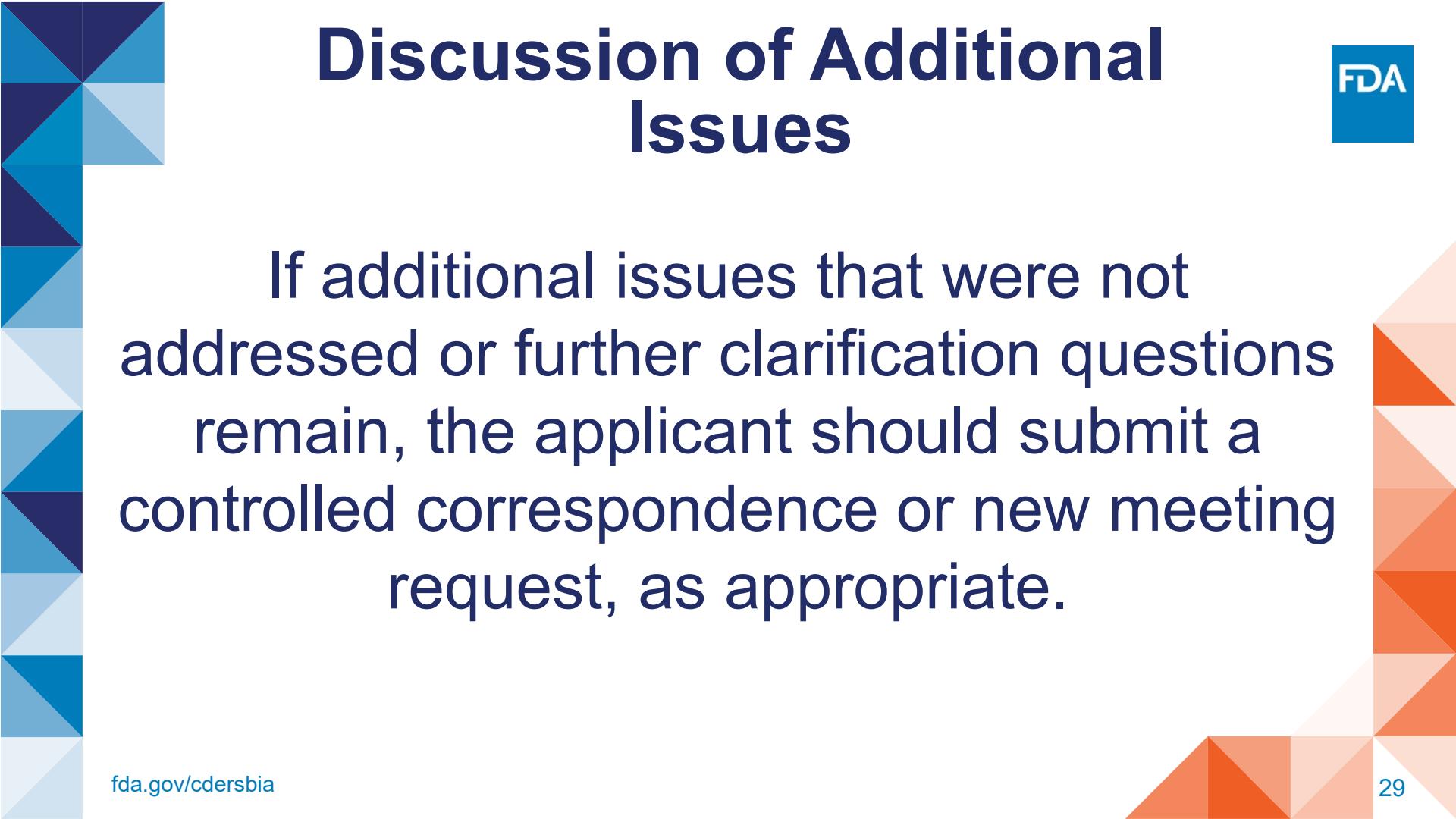
FDA-issued meeting minutes are considered the official record of the meeting



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
 - The addendum will also document any continued objections



Discussion of Additional Issues



If additional issues that were not addressed or further clarification questions remain, the applicant should submit a controlled correspondence or new meeting request, as appropriate.

Challenge Question #2

For PDEV meetings, what options do you, as the prospective applicant, have following receipt of the preliminary comments?

- a. Submit a revised agenda and presentation materials at least 48 hours of scheduled meeting
- b. Cancel meeting if the responses adequately address questions
- c. Change FTF meeting format to VC
- d. All of the above



Upcoming Webinar



FDA/SBIA Webinar: Pre-ANDA Pre-Submission Meeting Requests: Benefits for ANDA Submission and Approval

- Date: May 9, 2024, 1:00 – 3:30 P.M. E.T.
- Format: Virtual via Adobe Connect





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 as Complex Products for Generic Drug Development Purposes](#)
- Draft guidance for industry [Controlled Correspondence Related to Generic Drug Development](#) (December 2022)
- 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>
- MIE Webinar: <https://www.fda.gov/drugs/news-events-human-drugs/fda-ema-parallel-scientific-advice-psa-program-03162022>
- FDA-EMA Parallel Scientific Advice Program: <https://www.fda.gov/drugs/news-events-human-drugs/fda-ema-parallel-scientific-advice-psa-program-03162022>
- GDUFA III Enhancement to the Pre-ANDA Program: <https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iii-enhancements-pre-anda-program>



Questions?

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Backup Slides



Suitability Petitions and PDEV/PSUB Meeting Interactions



- Purpose of Suitability Petition:
 - A request to submit an ANDA that is different from the reference listed drug (RLD) in one or more of the following: strength, route of administration, dosage form, or a change in one active ingredient in a fixed-combination drug product (i.e., a drug product with multiple active ingredients)
 - An approved petition does not guarantee approval as an ANDA but allows it to be submitted for review as an ANDA
- If a product requires a suitability petition for ANDA submission, then FDA ***may*** grant a meeting request if
 - The suitability petition is approved and submitted as part of the meeting package for the specific product, ***and***
 - The meeting package meets the “will” or “may” grant situations for PDEV or PSUB meetings



Challenge Question #2

Which type of pre-ANDA scientific meeting can be submitted in the form of a draft meeting presentation?

- a. Product Development Meeting
- b. Pre-Submission Meeting

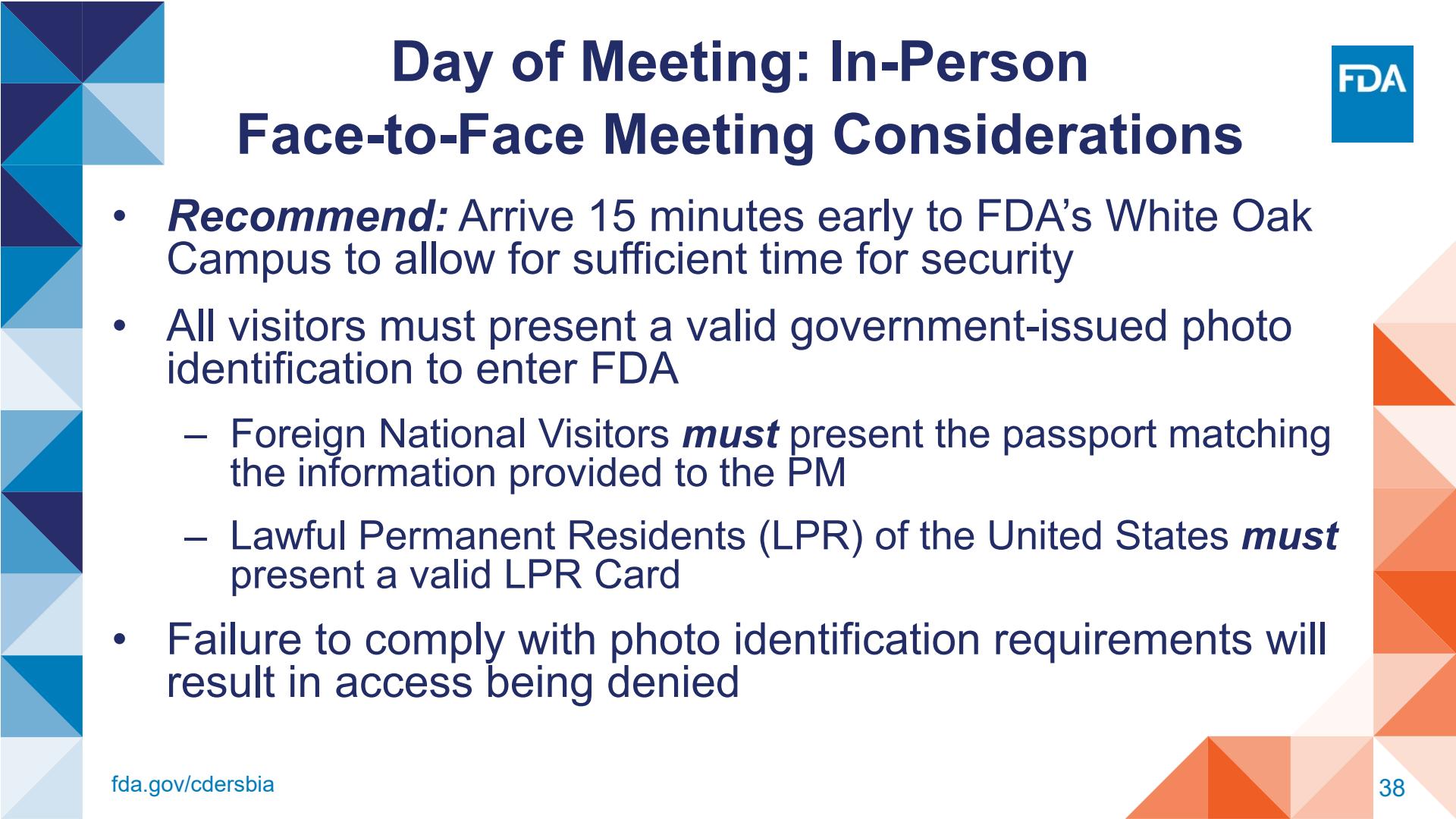


Specifics for In-Person Face-to-Face Meetings



At least 2 weeks prior to scheduled meeting date, provide the assigned project manager:

- Name, title, and company affiliation of individuals participating in meeting.
- If a hybrid meeting, indicate who is attending in person vs. virtually
- Relevant information for any foreign national visitors attending in person
 - Foreign Visitor Data Request Forms will be provided with the Meeting Information Letter
 - **Note:** Legal Permanent Residents (LPRs) of the United States are not required to submit a Foreign Visitor Data Request Form



Day of Meeting: In-Person Face-to-Face Meeting Considerations



- **Recommend:** Arrive 15 minutes early to FDA's White Oak Campus to allow for sufficient time for security
- All visitors must present a valid government-issued photo identification to enter FDA
 - Foreign National Visitors **must** present the passport matching the information provided to the PM
 - Lawful Permanent Residents (LPR) of the United States **must** present a valid LPR Card
- Failure to comply with photo identification requirements will result in access being denied