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

Maria Monroy-Osorio
Regulatory Health Project Manager
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)
CDER | U.S. FDA

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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
- GDUFA Reauthorization Performance Goals And Program: Enhancements Fiscal Years 2023-2027 (GDUFA III Commitment Letter): https://www.fda.gov/media/153631/download

Controlled Correspondence or PDEV Meeting?

Controlled correspondence (CC)	PDEV Meeting
• Single or small group of closely related questions • Questions outside of PDEV scope • Response within 60 days (Level 1) or 120 days (Level 2)	• 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

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- 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 number[1]
- 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

Refer to FDA Guidance for Industry Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA

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

Refer to FDA Guidance for Industry Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA

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 plan[1]
  - Do not request a TC or WRO meeting format

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

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

U.S. FOOD & DRUG ADMINISTRATION

Questions?

Maria Monroy-Osorio
Regulatory Health Project Manager
Office of Research and Standards | Office of Generic Drugs
CDER | U.S. FDA