GDUFA III
Redesigned Pre-Submission (PSUB) Meetings: What's New?

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SBIA Webinar: Redesigned Pre-Submission Meetings in GDUFA III:
Benefits for ANDA Submission and Approval
May 9, 2024

Outline

- Review of available pre-ANDA meetings
- Purpose of redesigned PSUB under GDUFA III
- PSUB eligibility criteria
- GDUFA II vs GDUFA III
- GDUFA III PSUB meeting package
- New meeting timeline
- Expectations for day of PSUB meeting

GDUFA III 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[1]

Pre-Submission (PSUB) Meetings

[1]For information on when a PDEV will or may be granted by FDA, refer to the GDUFA Reauthorization Performance Goals And Program Enhancements Fiscal Years 2023-2027 (GDUFA III Commitment Letter)

Non-GDUFA III 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) Pilot Program

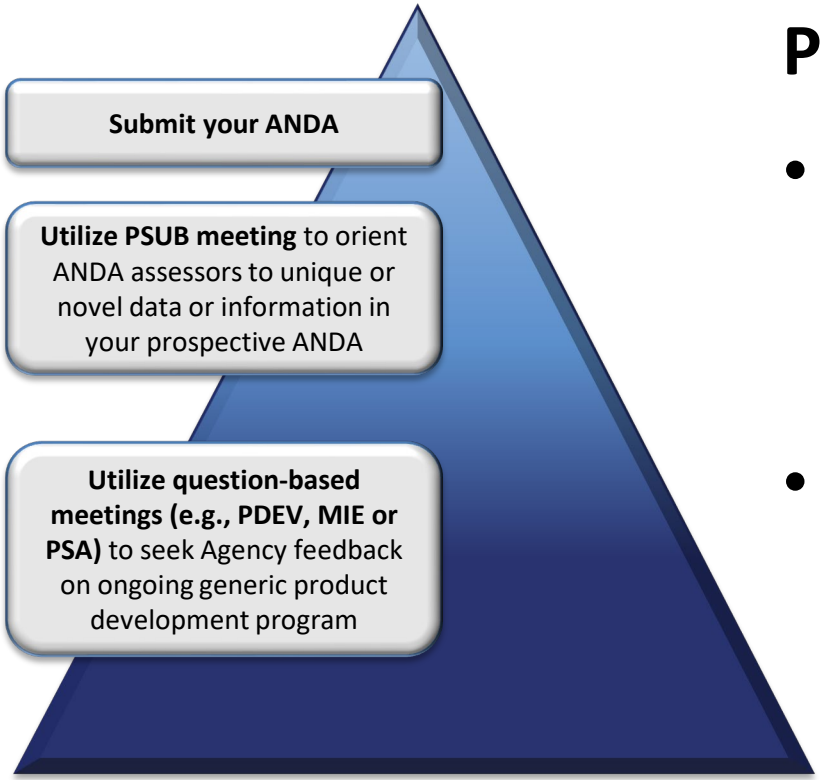
for Complex Generic/Hybrid Products

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
- Expanding Generic Drug Access Through International Engagements Webinar

Recommended Meeting Progression



PDEV, MIE and PSA meetings

- Scientific exchange to discuss specific issues or questions
- Targeted advice regarding ongoing ANDA development program

Purpose of Redesigned PSUB Meetings

- Provides a 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
  - ***IS NOT*** an opportunity to determine whether the ANDA is acceptable for receipt

GDUFA II vs GDUFA III

	GDUFA II	GDUFA III
Purpose	To discuss and explain content and format of upcoming ANDA submission	Opportunity to present unique or novel data or information in upcoming ANDA submission
Meeting Formats	In-person face-to-face, teleconference or written response only	In-person face-to-face or videoconference
Grant/Deny Goal Date	Within 14 days of FDA receipt	Within 30 days of FDA receipt
Preliminary Written Comments	Yes – Agency will provide written responses to questions in the meeting package NLT 5 days before scheduled meeting date	Yes[1] - Agency will provide written comment NLT 5 days before the scheduled meeting date
Hold Meeting Goal Date	Within 120 days of granting the meeting	Within 60 days of FDA receipt[2]
Meeting minutes	Yes – within 30 days of the meeting date	Yes – within 30 days of the meeting date

[1] If the Agency does not have preliminary comments to provide, the prospective applicant will be notified NLT 5 days prior to the scheduled meeting date.

[2] A shorter timeline (60 days) to allow timely feedback from the FDA

PSUB Meeting Eligibility

- ✓ FDA ***will*** grant a PSUB:
  - 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 assessment efficiency
    - Prospective ANDA applicants may request a PSUB meeting whether they had a PDEV meeting or not

PSUB Meeting Package

- Refer to the “Formal Meeting Guidance” before submitting
- Submit concurrently with the PSUB meeting request
- In general, high-level information is sufficient
- In general, ***should not*** include questions

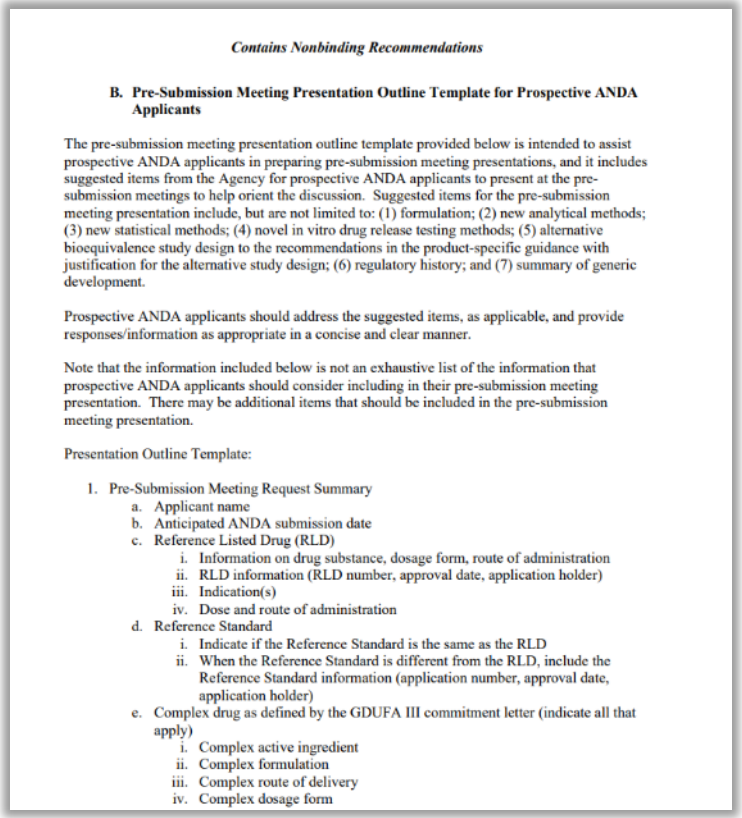
“Formal Meeting Guidance”: Guidance for industry *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA Guidance for Industry*

PSUB Meeting Package

- Meeting package should include the following, among other items:
  - If there were any prior PDEV meetings for the same proposed complex generic product
    - Event IDs for the prior PDEV meeting(s)
    - Summary of the advice provided from PDEV meeting(s)
  - ***If no prior PDEV meeting(s) were held***, an explanation for why a PSUB meeting should be granted
  - Estimated timeline for submission of the ANDA
  - Unique or novel data or information to be included in the ANDA submission

PSUB Meeting Package

- PSUB meeting package can be submitted in the format of a draft meeting presentation
  - For a suggested presentation outline template with recommendations on information that should be included, see **Appendix B** of the "Formal Meetings Guidance"



Contains Nonbinding Recommendations

B. Pre-Submission Meeting Presentation Outline Template for Prospective ANDA Applicants

The pre-submission meeting presentation outline template provided below is intended to assist prospective ANDA applicants in preparing pre-submission meeting presentations, and it includes suggested items from the Agency for prospective ANDA applicants to present at the pre-submission meetings to help orient the discussion. Suggested items for the pre-submission meeting presentation include, but are not limited to: (1) formulation; (2) new analytical methods; (3) new statistical methods; (4) novel in vitro drug release testing methods; (5) alternative bioequivalence study design to the recommendations in the product-specific guidance with justification for the alternative study design; (6) regulatory history; and (7) summary of generic development.

Prospective ANDA applicants should address the suggested items, as applicable, and provide responses/information as appropriate in a concise and clear manner.

Note that the information included below is not an exhaustive list of the information that prospective ANDA applicants should consider including in their pre-submission meeting presentation. There may be additional items that should be included in the pre-submission meeting presentation.

Presentation Outline Template:

1. Pre-Submission Meeting Request Summary
   a. Applicant name
   b. Anticipated ANDA submission date
   c. Reference Listed Drug (RLD)
      i. Information on drug substance, dosage form, route of administration
      ii. RLD information (RLD number, approval date, application holder)
      iii. Indication(s)
      iv. Dose and route of administration
   d. Reference Standard
      i. Indicate if the Reference Standard is the same as the RLD
      ii. When the Reference Standard is different from the RLD, include the Reference Standard information (application number, approval date, application holder)
   e. Complex drug as defined by the GDUFA III commitment letter (indicate all that apply)
      i. Complex active ingredient
      ii. Complex formulation
      iii. Complex route of delivery
      iv. Complex dosage form

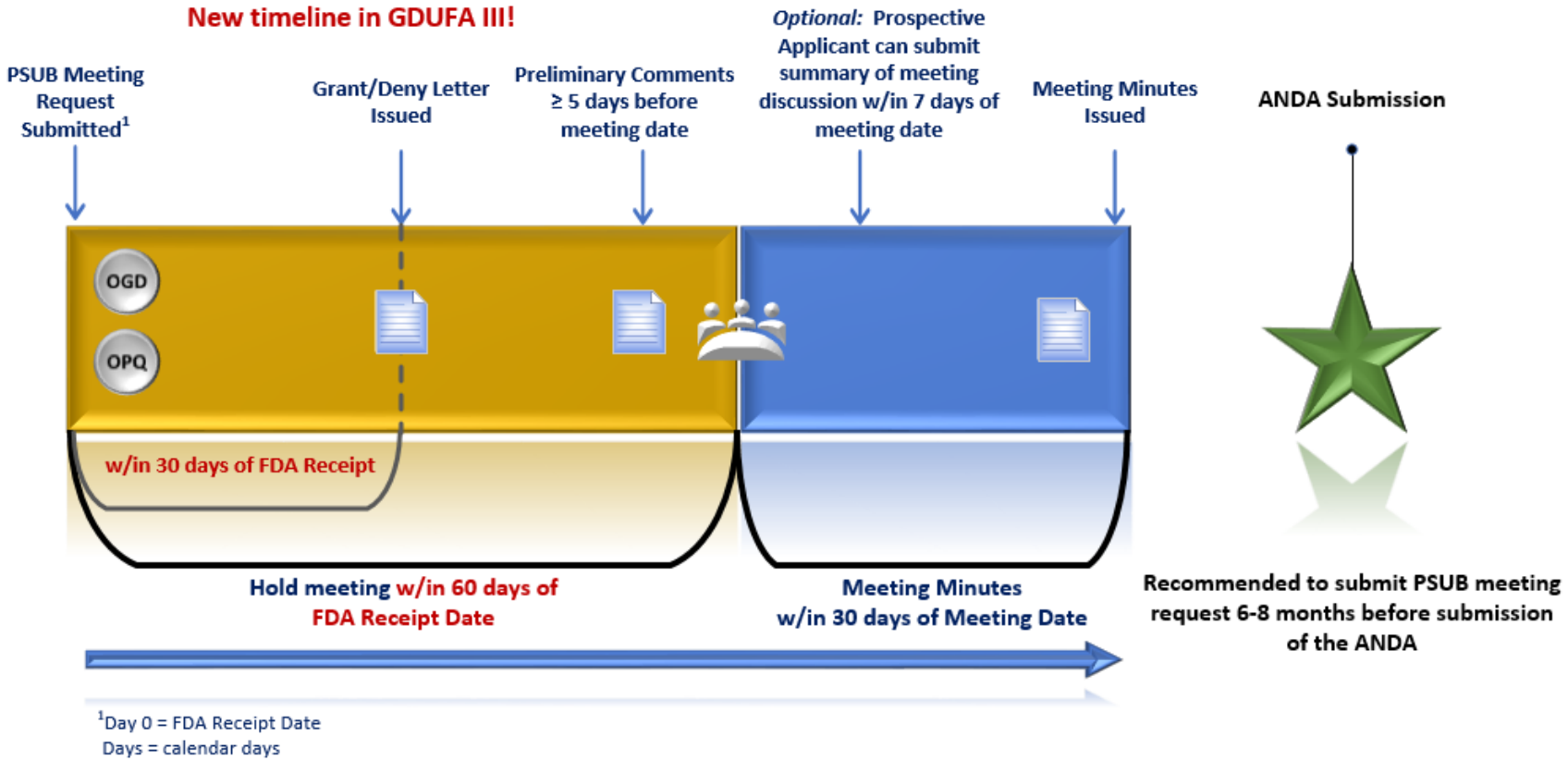
Refer to guidance for industry *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA Guidance for Industry*

PSUB Meeting Request/Package

- **Do** 
  - Include information on regulatory history (e.g., prior PDEV meetings, CCs)
  - List the 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 format of draft presentation
- **Don’t** 
  - Include questions[1]
  - 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*

PSUB Meeting Timeline



Meeting Day

- Meetings are typically 60 minutes
- Your presentation will help orient the discussion
- FDA attendees will include:
  - Members of the ANDA assessment team
  - Participants in prior PDEV meetings, if applicable
- At the meeting:
  - FDA can ask questions regarding information in your presentation
  - FDA ***will not*** address questions (e.g., acceptability for filing)
  - FDA ***will*** identify items or information that should be clarified before submission of the ANDA, when applicable

Summary

- GDUFA III redesigned PSUB meetings provide prospective applicants the opportunity to present unique or novel data or information that will be included in the upcoming ANDA submission
- FDA will identify any items or information that should be clarified before submission
- If you have questions for the Agency before submission of your ANDA, seek feedback through an appropriate pathway (i.e., either controlled correspondence or pre-ANDA product development meeting)

Resources

- GDUFA Reauthorization Performance Goals And Program Enhancements Fiscal Years 2023-2027 (GDUFA III Commitment Letter)
- 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)
- May 15, 2023, SBIA Webinar - *A Deep Dive: GDUFA III Scientific Meetings*

For general questions related to GDUFA III PSUB meetings, contact PreANDAHelp@fda.hhs.gov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