Overview of Pre-ANDA Meetings Under GDUFA III

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Learning Objectives

- Identify the purpose and scope of pre-ANDA product development and pre-submission meetings
- Describe the new features of pre-submission meetings under GDUFA III
- Illustrate best practices for preparation of a pre-ANDA meeting request and package
- Clarify when to utilize controlled correspondence in lieu of a pre-ANDA meeting

Goals of Pre-ANDA Program

- Clarify regulatory expectations for prospective applicants 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 needed to obtain ANDA approval

Pre-ANDA Meetings

Pre-ANDA meetings were introduced in GDUFA II to facilitate pre-submission communications with the FDA and a prospective applicant to discuss questions related to a complex product and/or complicated drug development questions

GDUFA: Generic Drug User Fee Amendments

GDUFA III Commitment Letter

GDUFA III Pre-ANDA-Meetings

Product Development (PDEV) Meeting

No change from GDUFA II

Pre-Submission (PSUB) Meetings (Redesigned)

New Scope and Timeline in GDUFA III

Guidance for Industry: The Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA *(Oct 2022);*
GDUFA Reauthorization Performance Goals And Program: Enhancements Fiscal Years 2023-2027: https://www.fda.gov/media/153631/download

Pre-ANDA Meetings: Before ANDA Submission

Product Development (PDEV)

- Scientific exchange to discuss specific issues or questions (e.g., a proposed study design, alternative approach, or additional study expectations)
- Targeted advice regarding ongoing ANDA development program
- Prospective ANDA applicants may request more than one product development meeting

Pre-Submission (PSUB)

Redesigned in GDUFA III!

- **What:** Prospective applicant has opportunity to present ***unique*** or ***novel*** data or information that will be included in the ANDA submission
- **Why:** Communicate to the FDA to enable efficient review and improve chances of first cycle approval
- **How:** FDA will not provide a substantive assessment of summary data or full study reports at the meeting. However, at the meeting, FDA will identify items or information that should be clarified before submission of the ANDA.
- **When to request:** ANDA is anticipated to be submitted approx. 6-8 months after submission of the meeting request

PDEV Meeting Eligibility – Will Grant

FDA ***will*** grant a prospective applicant a Product Development Meeting if, in FDA's judgment:

1. The requested meeting 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 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 for discussion
3. A Controlled Correspondence (CC) response would not adequately address the prospective applicant's questions; and
4. A Product Development Meeting would significantly improve ANDA assessment efficiency.

PDEV Meeting Eligibility – May Grant

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. Meeting package is complete
3. Questions could not be adequately addressed through a CC, and
4. A meeting would significantly improve ANDA assessment efficiency

PSUB Meeting Eligibility

- FDA ***will*** grant a prospective applicant of a complex product a PSUB Meeting
  - If the prospective applicant was granted a PDEV Meeting for the same Complex Generic Product **or**
  - If FDA believes in its sole discretion that the PSUB meeting would improve ANDA assessment efficiency
- FDA recommends that a prospective ANDA applicant of a complex product seek FDA's input via a PDEV meeting prior to submitting a request for a PSUB meeting so that FDA has knowledge of the prospective ANDA applicant's development program at the time of the PSUB meeting
- However, prospective ANDA applicants can request a PSUB meeting whether they had a PDEV meeting or not

Meeting Formats Under GDUFA III

PSUB

- **In-person face-to-face meetings** (FTF) are those in which core staff participate in person at the FDA
  - Additional attendees can participate virtually via a video connection, as needed (e.g., a hybrid meeting format)
- **Videoconferences** (VC) are meetings in which the attendees participate from various remote locations via a video connection

PDEV

- **Teleconference** (TC) means a verbal communication by telephone
- **Written response only** (WRO) responses are sent in lieu of a meeting or teleconference when requested by or otherwise agreed to by the applicant

Guidance for Industry: The Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA (Oct 2022)

Videoconference (VC) ≠ Teleconference (TC)

- FDA uses the same platform (e.g., Zoom) to conduct TC and VC, but they are not the same
  - VCs allow for both audio and visual communication with applicants which not only facilitate discussion but also can serve as an alternate to in-person FTF meetings
  - TCs are voice only with no projection of presentation materials or use of video/camera
- Teleconferences are more appropriate for clarification questions
  - Specific meeting types are strictly TC (e.g., PSG teleconferences, post-CRL clarification)
- For scientific meetings, like pre-ANDA meetings, VC is typically more efficient than TC considering the complexity of the scientific nature of the discussion
- Applicants should request the desired meeting format in the meeting request
  - **e.g., DO NOT request a VC if you want an in-person FTF mtg, DO NOT request a TC if you want a VC!**
- FDA will confirm the meeting format at the time of granting the meeting

Pre-ANDA Meeting Format/Timeline

New timeline in GDUFA III!

	Product Development	Pre-submission
Format of the Meeting	In-person FTF, VC, TC[1] or WRO[1]	In-person FTF or VC
Grant/Deny Decision Timeline	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 meeting being granted[2]	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 (min)	60	60
Meeting Minutes	w/in 30 days of meeting date	w/in 30 days of meeting date

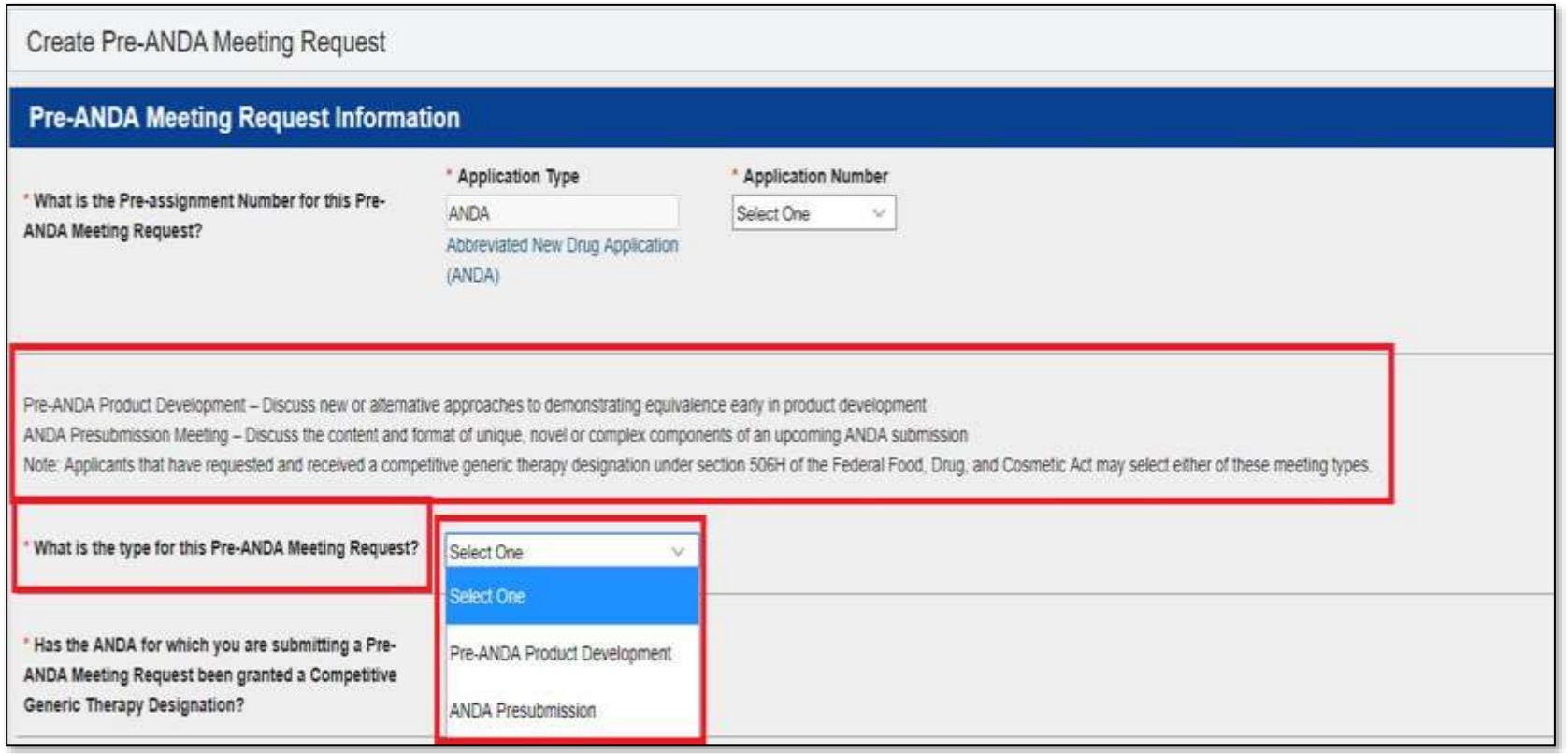
[1] FDA may grant a TC or WRO if requested by the applicant or if FDA grants the meeting above and beyond the commitment letter
[2] If a PDEV is granted as WRO, the written response will be issued within 120 days of the grant date.

Submitting Your Meeting Request

- Obtain a pre-assigned ANDA number

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

- Submit via the CDER Direct NextGen Collaboration Portal



PDEV Meeting Package: Format and Content

- Provide specific proposals and questions supported by appropriate data and scientific justification
- A brief statement indicating how the product meets the criteria for a complex product
- A background section that includes the history and status of your product development
- Each question is followed by a corresponding justification, rationale or data to support discussion as applicable
- List of questions grouped by discipline (e.g., BE, CMC, etc.)
- Each question clearly numbered (e.g., 1,2,3 without sub-questions)

Refer to guidance for industry *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA Guidance for Industry* (October 2022)

PSUB Meeting Package: Format and Content

- Indicate if there was a prior PDEV meeting with FDA for the same complex product and provide event IDs for previously granted PDEV meeting(s), if applicable
  - If no PDEV meeting was held, explain why a PSUB meeting should be granted
- Include a summary of the advice provided at the PDEV meeting(s)
- Outline the unique, novel, or complex aspects of your upcoming submission
- Estimated timeline for submission of the ANDA
- Meeting package can be submitted in the format of a draft meeting presentation
  - For a suggested pre-submission meeting presentation outline template with recommendations on information that should be included, see Appendix B of the "formal meeting" guidance (see below)

Refer to guidance for industry *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA Guidance for Industry* (October 2022)

More Tips

- Before submitting, read all applicable guidances and standards
- For PDEV meetings
  - Ask specific questions about your development plan, proposed approach/method, study design, etc.
  - Provide sufficient justification and preliminary data (as needed) to support proposals
  - No data dumping
  - Do not ask questions that are pertaining to assessment issues (e.g., acceptance criteria for specification, acceptability of the study results, etc.)
- For PSUB meetings
  - Draft presentation may be updated up to 21 days prior to the meeting date so that FDA may provide preliminary comments on the presentation 5 days before the meeting

Meeting Request Evaluation
Grant/Deny Decision

- Parallel assessments of the meeting request by the Office of Generic Drugs (OGD) and the Office of Pharmaceutical Quality (OPQ)
  - Meeting request assessment team reviews the product details, contents, and submitted questions*
  - OGD and OPQ coordinate to provide a unified grant/deny decision

** Questions are not generally anticipated for PSUB meetings*

Your Meeting Was Granted

- Typically granted as an in-person FTF or videoconference meeting, though the applicant may request a teleconference or written response only for a PDEV meeting
  - Beginning March 27, 2023, applicants can request in-person FTF meetings for PDEV or PSUB meetings
- A project manager from the Office of Research and Standards (ORS) or OPQ is assigned as the point of contact

Pre-ANDA Meeting Package Assessment

- After a PDEV meeting is granted, FDA staff will assess the meeting package, request consults and send information requests (as needed)

- **Information Requests (IR) for PDEV**
  - Sent to prospective applicant through the portal
  - FDA strives to send early in the process, but can be sent at any point
  - Prospective applicant responds to the IR via the portal

- **Information Requests (IR) for PSUB**
  - Will not generally be issued for PSUB Meetings
  - FDA will identify additional content for the meeting in the grant letter, including topics that should be addressed in the meeting in addition to those identified in the meeting request by the applicant

Preliminary Responses or Comments

Product Development (PDEV)
No change from GDUFA II

- Preliminary written comments will be sent via the portal NLT 5 calendar days before scheduled meeting date
- Your opportunity to focus your meeting
  - Submit a revised agenda
  - Submit presentation materials (not required)
  - Submit these through the portal at least 48 hours prior to scheduled meeting
- Should NOT generate the submission of new questions
- Applicant can cancel the meeting if preliminary responses adequately address their questions **or**
- Applicant can request change in meeting format (e.g., from in-person FTF to VC or TC) if discussion is needed for clarification of only some of the original questions

Pre-Submission Meetings
New Format in GDUFA III

- Preliminary written comments will be sent via the portal NLT 5 calendar days before scheduled meeting date
  - FDA may indicate that there is no comment
- Your opportunity to focus your meeting
  - Submit presentation materials
  - Submit through the portal at least 48 hours prior to scheduled meeting
- Preliminary comments from the FDA should not result into cancellation of PSUB meeting

In-Person Meetings

- ***At least 2 weeks prior to the scheduled meeting date*** provide the assigned Project Manager (PM):
  - Name, title, and company affiliation of all individuals participating in the meeting
  - Relevant information (e.g., country of citizenship, passport information, etc.) for any Foreign National (FN) visitors participating in person
    - Foreign Visitor Data Request Form will be included with the Meeting Information Letter
- ALL visitors must present a valid government-issued photo identification on the day of the meeting
  - An FN visitor ***must*** present the passport that matches information provided to the PM or that individual will be denied entry
  - Lawful Permanent Residents (LPR) of the U.S. ***must*** present a valid LPR card. Other forms of identification will not be accepted

Meeting Day

- Meetings are typically 1 hour
- **For PDEV Meetings:**
  - Discussion should focus on clarification of the Agency's preliminary written comments
  - Participants discuss the data, questions, and the responses provided to assist the prospective ANDA applicant's complex product development program
  - FDA **will not** address or discuss new data or questions not presented in the original meeting package
- **For PSUB Meetings:**
  - Presentation for a PSUB meeting to help orient the discussion
  - Members of the ANDA assessment team will be in attendance as well as participants in prior PDEV meetings, if applicable

Meeting Minutes

- If a prospective applicant would like FDA to consider their meeting summary:
  - Submit within 7 calendar days of the meeting via the portal
- FDA will issue meeting minutes within 30 calendar days after the meeting date
- FDA-issued minutes are considered the official record of the meeting

Dispute of Meeting Minutes

- A prospective applicant requesting additional clarification of the meeting minutes issued by FDA should contact the assigned FDA point of contact (POC)
- FDA recommends any concerns about the meeting minutes be submitted in writing to FDA within 10 calendar days of receipt
  - If the minutes are determined to accurately and sufficiently reflect the meeting discussion, the POC will convey this decision to the applicant, and the minutes will stand as the official documentation of the meeting.
  - If, after discussions with the applicant, FDA deems it necessary to change the official minutes, the changes will be documented in an addendum to the official minutes. The addendum will also document any continued objections.

CC or PDEV Meeting?

- **Controlled Correspondence (CC)**
  - Single or small group of closely related questions
  - When questions are outside of the scope of a PDEV meeting request
  - Response within 60 (Level 1) or 120 (Level 2) calendar days
  - Following a PDEV meeting, applicant seeking further clarification or has new questions related to what was discussed at the meeting
- **PDEV Meeting**
  - Best for multidisciplinary questions
  - New information, data, or questions that will not be adequately addressed in a controlled correspondence
  - PDEV Meeting held within 120 days of being granted
  - ***Do not*** submit the same question through CC and pre-ANDA PDEV meeting request around the same time

Upcoming SBIA Webinar on PSUB Meetings

- **Title:** "A Deep Dive: GDUFA III Scientific Meetings"
- **Date:** May 15, 2023, 1- 4:30 PM EDT
- **Objectives:**
  - Provide an in-depth look into the enhancements and new features of GDUFA III scientific meetings
  - Describe how and when to utilize these meetings to support generic drug development
  - Provide clarification and best practices in meeting request and conduct
- **Topics covered:**
  - Pre-Submission Meetings
  - Post-Complete Response Letter (post-CRL) Scientific Meetings
  - Product-Specific Guidance (PSG) Teleconferences, and Pre- and Post-submission PSG Meetings

Challenge Question 1

For a **PDEV meeting request** for a complex generic product to be granted, which of the following, in FDA's judgment, is true

a) The prospective applicant submits a complete meeting package

b) A controlled correspondence would not adequately address the prospective applicant's questions

c) The meeting would significantly improve ANDA assessment efficiency

d) a, b, and c

Challenge Question 2

A **pre-submission meeting** provides an applicant the opportunity to discuss and explain the format and content of an ANDA to be submitted.

a. True
b. False

Resources

- GDUFA Reauthorization Performance Goals And Program: Enhancements Fiscal Years 2023-2027 (GDUFA III Commitment Letter): https://www.fda.gov/media/153631/download
- 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)
- GDUFA III Enhancement to the Pre-ANDA Program: https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iii-enhancements-pre-anda-program