U.S. FOOD & DRUG ADMINISTRATION

GDUFA III
Product-Specific Guidance (PSG) Meetings

Hee Sun Chung
Lead Pharmacologist
Division of Bioequivalence I, Office of Bioequivalence
Office of Generic Drugs
CDER | U.S. FDA

A Deep Dive: GDUFA III Scientific Meetings – May 15, 2023

Learning Objectives

- Describe scope of and eligibility for PSG meeting
- Describe communication process for meeting grant/deny decision
- Explain timeline and process for PSG meeting
- Describe communication process for preliminary written communication

Topics Not Covered

- Where to submit pre-submission and post-submission PSG meeting request
- Meeting minutes
- Dispute of minutes

Refer to GDUFA III PSG Teleconference presentation for above information.

Acronyms

- Teleconference: TC
- Meeting: Mtg
- Meeting Request: MR
- Discipline Review Letter: DRL
- Complete Response Letter: CRL
- Controlled Correspondence: CC
- Product Development Mtg: PDEV mtg
- Enhanced Mid-cycle Review Mtg: EMCRM
- Bioequivalence: BE

GDUFA III Commitment Letter

- FDA agreed to certain time frames and procedures for scheduling and conducting:
  - PSG TC: to provide feedback on the potential impact of a new or revised PSG on the applicant's development program
  - **PSG mtg**: to provide a forum in which the applicant can discuss the scientific rationale for an approach other than the approach recommended in the PSG to ensure that the approach complies with the relevant statutes and regulations

Scope

- Discuss questions related to proposed alternative BE approach which differs from the recommendations in current PSG
- **Will not** discuss questions unrelated to alternative BE approach to recommendations in the current PSG

PSG TC/Mtg Overview

* Examples

- PDEV mtg in pre-submission stage
- EMCRM or post-CRL scientific mtg in post-submission stage

Timeline and Format (if mtg is granted)

Mtg Type	Grant/Deny Decision	Mtg Held	Duration	Format	Minutes
Pre-Submission PSG Mtg	Within **14** days of receipt	Within **120** days of receipt	60 minutes	In-Person Face-to-Face, Videoconference, TC, or Written Response	Within **30** days after PSG mtg
Post-Submission PSG Mtg		Within **90** days of receipt			

Days = calendar days

Eligibility

- Available for both complex and non-complex drug products
- One PSG MR for each new or revised PSG
- Already had PSG TC, in the <u>same phase</u> as PSG MR
- If post-submission PSG mtg, applicant has not responded to possible BE deficiency identified in DRL or BE deficiency identified in CRL

PSG TC and PSG Mtg in Same Phase

Reasons for Deny: Pre-submission PSG Mtg

- FDA intends to **deny** if,
  - No pre-submission PSG TC, or
  - ANDA submitted after pre-submission PSG TC
- FDA **may deny** if,
  - MR is incomplete
  - Inquiry would be appropriately addressed through a CC, or
  - Same or similar questions were submitted in a request for another mtg type or in CC

Reasons for Deny: Post-submission PSG Mtg

- FDA intends to **deny** if,
  - No post-submission PSG TC, or
  - PSG TC held in pre-submission stage, and then ANDA submitted
- FDA **may deny** if,
  - MR is incomplete
  - Inquiry would be appropriately addressed through a CC
  - Same or similar questions submitted in a request for another mtg type or in CC
  - Questions in mtg package have been addressed during ANDA assessment, or
  - Applicant responded to possible BE deficiency identified in a DRL or BE deficiency identified in CRL

Partial Grant and New MR

- MR may be granted in part for questions that are appropriate for mtg type requested and denied in part for questions not appropriate for mtg type requested.
- If MR is denied, subsequent request to schedule pre- or post-submission PSG mtg will be considered a new request.

Grant/Deny Notification

- Written notification of grant/deny decision
- If denied, written notification will include an explanation of reason for denial
- If granted and FDA will be providing written responses only instead of holding a mtg, FDA will advise applicant that a written response only is forthcoming

Timing of PSG MR: Pre-Submission

- In timely manner after pre-submission PSG TC
- Consider time needed to develop the mtg package for and before submitting the ANDA

Timing of PSG MR: Post-Submission

- Consider status of ANDA and its assessment cycle as well as time needed to develop the mtg package.
- Allow FDA to complete its scientific evaluation of evidence of BE submitted in ANDA (e.g., refrain from requesting post-submission PSG mtg during assessment cycle until after FDA has issued a DRL or a CRL).

One Mtg at a Time

- Should not request PSG mtg if applicant has requested or has been granted but not yet had another mtg (e.g., pre-submission mtg, EMCRM, or post-CRL scientific mtg) with FDA.
- FDA recommends that applicants not submit a CC and a request for a pre- or post- submission PSG mtg at or around same time with same or similar questions.
- In case of multiple requests containing same or similar question(s), FDA intends to determine which request to grant and may deny the other(s).

Other Options for Feedback

- CC or another mtg type (e.g., PDEV, EMCRM, post-CRL scientific) based on scope of question and eligibility
- Consider types of questions, status of ANDA, and eligibility in determining pathway to seek FDA's feedback

Mtg Package Content

- Identify mtg type (i.e., pre- or post-submission PSG mtg) on cover page.
- Propose mtg format.
- Include date PSG TC was held and event ID.
- Include specific alternative approach to establishing BE, with justification, rationale, and data to support discussion.
- Submit mtg package and mtg request concurrently.
- For detailed information on content of cover page, mtg request, and mtg package, refer to draft Guidance for Industry *Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA*.

Rescheduling Mtg

- PSG mtg may be rescheduled if, for example,
  - Additional information is needed from applicant
  - Essential attendees are no longer available for scheduled date and time because of an emergency
  - Attendance by additional FDA offices not originally anticipated or requested is critical and offices' availability precludes holding mtg on original date
  - There is a pending regulatory policy issue that may affect response to questions
  - Federal government is closed or opening is delayed due to inclement weather, emergency, or other reason
- If PSG mtg needs to be rescheduled, should not submit new MR.

Pre-Mtg Communication

- FDA intends to provide preliminary written comments 5 calendar days before the mtg (unless FDA is providing a written response only).
- Preliminary written comments should not generate the submission of new questions.
- Provide updated agenda with list of questions for discussion no later than 48 hours before the mtg.
- If satisfied with preliminary written comments, applicant may cancel the mtg.
- Preliminary written comments not construed as final unless there is agreement between applicant and FDA that additional discussion is not necessary for any question or a particular question is considered resolved.

Cancelling PSG Mtg

- Possible reasons for cancelling PSG mtg
  - ANDA or prospective ANDA applicant withdraws MR
  - ANDA or prospective ANDA applicant informs FDA that its questions have been adequately answered by preliminary written comments
  - For pre-submission PSG mtg, prospective ANDA applicant submits ANDA
  - For post-submission PSG mtg, FDA refuses to receive the ANDA or applicant responds to possible BE deficiency identified in DRL or BE deficiency identified in CRL
- If PSG mtg cancelled, subsequent PSG MR considered new request

Day of Mtg

- Presentation not required (mtg time not extended to accommodate them)
- Discussion focused on clarification of preliminary written comments
- FDA **will not** address or discuss new data or questions not presented in original mtg package (can provide general advice or considerations)

Challenge Question #1

Which of the following statements is NOT true?

A. PSG TC should have been granted and held before PSG mtg can be requested.

B. With each new/revised PSG, ANDA applicant can request one PSG mtg.

C. Both complex and non-complex products are eligible for PSG mtg.

D. Pre-submission PSG mtg will be held within 90 days of MR.

Challenge Question #2

Which of the following statements is NOT true?

A. After pre-submission PSG TC, pre-submission PSG mtg may be requested if ANDA has not been submitted.

B. Post-submission PSG mtg should occur before responding to a possible BE deficiency identified in a DRL or BE deficiency identified in CRL.

C. Mtg agenda cannot be updated after MR submission.

D. FDA will not address or discuss new data or questions not presented in original mtg package.

PSG Mtg Summary

Scope	Discuss questions related to proposed alternative BE approach which differs from the recommendations in the current PSG
Eligibility	Already had PSG TC in same phase as PSG MR
Product Complexity	Both complex and non-complex drug products
Grant/Deny Decision	Within **14** days of receipt
Timeline for Mtg	Within **120** days of receipt for pre-submission Within **90** days of receipt for post-submission
Format	In-Person Face-to-Face, Videoconference, TC, or Written Response
Length	60 min
Other Options	CC or other mtg types (e.g., PDEV, EMCRM, post-CRL scientific) based on scope of question and eligibility

Resources

- GDUFA III Commitment Letter (https://www.fda.gov/media/153631/download)
- GDUFA III: Summary of Teleconferences and Meetings (https://www.fda.gov/media/162239/download)
- Draft Guidance for Industry: Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA (Feb 2023, https://www.fda.gov/media/165468/download)
- Product-Specific Guidances for Generic Drug Development (https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development)
- Draft Guidance for Industry: Controlled Correspondence Related to Generic Drug Development (Dec. 2022, https://www.fda.gov/media/164111/download)

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