U.S. FOOD & DRUG ADMINISTRATION

GDUFA III Product-Specific Guidance (PSG) Teleconferences

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

Learning Objectives

- Describe the PSG Teleconference Process Flow and Timeline
- Break Down the Elements of Pre-submission and Post-submission PSG Teleconferences
- Explain When, What, and How to Submit Your PSG Teleconference Request
- Identify Reasons for Granting and Denying Your PSG Teleconference
- Describe How FDA Will Schedule and Hold the PSG Teleconference
- Explain Canceling/Rescheduling the Teleconference, Issuing FDA Minutes, and Dispute of Minutes Process

PSG Teleconference Process Flow

- Pre-ANDA phase (CDER Direct NextGen Collaboration Portal)
- Post-ANDA phase (Electronic Submissions Gateway)
- Applicant can request a Written Response Only (WRO) or Teleconference (TC)
- No Information Request (IR) or Preliminary Written Comments issued for PSG TC
- All days noted are in calendar days

PSG Teleconference

FDA provides feedback on potential impact of new/revised PSG on a development program

- When a new or revised PSG is published on or after 10/1/2022, and an applicant or prospective applicant has already commenced or completed an in vivo bioequivalence study
- Commenced: the study protocol has been signed by the study sponsor and/or the contract research organization

- PSG TC is *not intended for in-depth scientific discussion*
- Can be requested in the pre-ANDA phase or after ANDA submission

PSG Teleconference

Grant/Deny decision	Teleconference held	Meeting duration	Meeting format
Within 14 days of FDA receipt of the request[1]	Within 30 days of FDA receipt of the request[2]	60 min	Teleconference or Written Response Only (WRO)[3]

[1]Commitment letter does not define a timeframe for the grant/deny decision. FDA anticipates a decision will be made within 14 days of FDA receipt.

[2]Goal only applies to requests submitted within 60 days of the PSG publication.

[3]If request meets the criteria in the GDUFA III Commitment Letter for a PSG Teleconference, FDA will generally grant the applicant's requested format. If a request does not meet the criteria, it's FDA's discretion to grant WRO or direct applicant to submit a controlled correspondence instead of holding a PSG TC.

PSG Teleconference Overview

- An applicant can request <u>only one PSG TC for each new or revised PSG</u> to discuss potential impact on their development program
- Teleconference means a verbal communication by telephone (audio only)
- Written response only are responses sent in lieu of a teleconference
- In general, FDA will not provide preliminary written comments
- Information requests will not be issued

When Should I Submit a PSG TC Request?

- FDA issues a notice in the *Federal Register* announcing the availability of new and revised PSGs posted on the PSG web page, *Product-Specific Guidances for Generic Drug Development*
  - Generally, FDA publishes PSG in batches on a quarterly basis
- Recommend applicant submits a PSG TC request within 60 calendar days after publication (i.e., date recommended) of the new or revised PSG

Newly Added Guidances since February 16, 2023

Excel CSV PDF

Show 10 entries Filter:

Active Ingredient (link to Specific Guidance)	Type	Route	Dosage Form	RLD or RS Number	Date Recommended
Afamelanotide	Draft	Subcutaneous	Implant	210797	02/16/2023
Bismuth Subsalicylate; Metronidazole; Tetracycline Hydrochloride	Draft	Oral	Tablet, Chewable, Tablet, Capsule	050719	02/16/2023
Cabotegravir; Rilpivirine	Draft	Intramuscular	Suspension, Extended Release	212888	02/16/2023
Dexmethylphenidate Hydrochloride; Serdexmethylphenidate Chloride	Draft	Oral	Capsule	212994	02/16/2023
Dihydroergotamine Mesylate	Draft	Nasal	Spray, Metered	213436	02/16/2023

When To Submit PSG Teleconference Request

- When FDA publishes a new or revised PSG that introduces or revises a recommendation related to an in vivo BE study and the applicant has already ***commenced or completed an in vivo BE study***

For Post-submission Only (Not described in GDUFA III Commitment Letter)*:

- When FDA publishes a new PSG which includes a recommendation to conduct an in vivo BE study and the ***ANDA applicant did not conduct an in vivo BE study****

- FDA publishes a revised PSG which includes a recommendation to conduct an in vivo BE study, the previous PSG did not include a recommendation to conduct an in vivo BE study, and the ***ANDA applicant commenced or completed the in vitro BE study or studies*** that were either recommended by FDA in the previous PSG or that the ANDA applicant decided to pursue after a prior product development meeting

* FDA offers the ability to request a PSG teleconference to applicants under this scenario even though such applicants may not meet all the criteria in the GDUFA III commitment letter.

When Not to Submit a Post-Sub PSG Teleconference

- When a PSG is revised to include an in vivo BE study as an additional option to the in vitro BE study that was recommended in the previous PSG and the ANDA applicant followed the recommendations in the previous PSG

What Should be Included in Your TC Request/Package

- A valid pre-assigned ANDA number or ANDA number
- Meeting type being requested (i.e., PSG Teleconference)
- Month and year the current PSG was published
- A description of how the applicant's study differs from the recommendations in the PSG, and if applicable, a statement indicating that the in vivo study is impacted by the new or revised PSG
- Signature page of the relevant in vivo BE study protocol signed by the study sponsor and/or contract research organization, if applicable
- Background section that includes: brief history of development program, status of product development, statement of purpose, and objectives of the TC
- The meeting package should provide information relevant to the discussion topics and enable FDA to prepare adequately for the meeting.
- The requested format and a proposed agenda outlining how the 60-minute time allotted should be apportioned to each agenda item

** The meeting package should be received at the time of the meeting request*

How to Submit a Pre-Sub PSG Teleconference

- A prospective ANDA applicant should submit a request for a pre-submission PSG TC electronically through the CDER Direct NextGen Collaboration Portal at https://edm.fda.gov/
- The cover page should identify the submission as a PSG Teleconference Request

Pre-Sub PSG TC Request CDER NextGen Portal

Application Type

ANDA

Abbreviated New Drug Application (ANDA)

* Application Number

Select an option..

Applicant required to provide ANDA pre-assignment number

* What is the type for this Pre-ANDA Meeting Request?

Select One

add

Pre-ANDA Product Development

ANDA Pre-Submission Meeting

Pre-Submission Product Specific Guidance Teleconfere...

Pre-Submission Product Specific Guidance Meeting

New pre-ANDA meeting types added for selection

Pre-Submission PSG Teleconference - To obtain Agency feedback on potential impact of a new or revised PSG for a prospective applicant's drug development program

Pre-Submission PSG Meeting - To obtain additional Agency feedback on the scientific rationale for an approach other than the bioequivalence approach recommended in a PSG after a PSG Teleconference and prior to ANDA submission.

PSG Teleconference description

Pre-Sub PSG TC Request CDER NextGen Portal

If PSG Recommendation Date Before 10/1/22:

Logic added to allow PSG Tcon for PSG posted on or after 10/1/2022

If Protocol Signature after PSG Recommendation:

Protocol signature date should be before PSG recommendation date

How to Submit a Post-Sub PSG Teleconference

- An ANDA applicant should submit a request for a post-sub PSG TC electronically through the Enterprise Submission Gateway
- Request should be submitted as GI* Amendment
- The cover page should identify the submission as a PSG Teleconference Request
- eCTD submission guidance at https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd

* *General Information*

Teleconference Request Granted

- FDA will provide written notification to the applicant of the decision and format (i.e., TC or WRO)
- Scheduling information is provided in the grant letter or as soon as possible following granting the request
- If FDA is providing written responses only, instead of holding a TC, FDA will notify the applicant of the WRO format
- FDA schedules the TC by determining the date, time, length, format and expected FDA participants
- Teleconferences are scheduled within the GDUFA III performance goals if TC request is received within 60 days of PSG publication
  - which is 30 days from receipt of the TC request

Teleconference Request Denied

- If the applicant's in vivo BE study started after the PSG was published or the request is incomplete

- When FDA publishes a new or revised PSG which includes a recommendation to conduct an in vitro BE study and if the applicant has commenced or completed an in vivo BE study, submission of the in vivo BE study is generally an acceptable approach for demonstrating BE

  - FDA recommends, an applicant include supporting information with its ANDA to justify the in vivo approach used that deviates from the in vitro approach recommended in the PSG to demonstrate BE

* *If a teleconference request is denied, written notification to the applicant will include an explanation of the reason for the denial. A subsequent PSG TC request is considered a new request and assigned new timeframes.*

Day of Your Teleconference

- Teleconference is typically one hour
- Discussion will focus on how the applicant's BE studies differ from the studies recommended in the PSG
- FDA ***will not*** address or discuss any new data or questions outside the scope of the PSG teleconference. FDA can provide general advice or recommendations
- Generally, applicant will be asked to summarize important discussion points, agreements, and action items to ensure mutual understanding of meeting outcomes and action items

PSG Teleconference Outcomes

- Obtain FDA's feedback on the applicant's development program
- Additional clarification or discussion needed →FDA will recommend a path for future communication*
    - Controlled correspondence
    - Pre- or post-submission PSG meeting
    - Other meeting type, as appropriate

** Applicants should not submit multiple meeting requests or controlled correspondence at or around the same time with the same or similar questions*

Teleconference Minutes

- Teleconference minutes are issued within 30 calendar days after the teleconference
- Applicant may submit their summary within 7 calendar days of the meeting date
- FDA-issued minutes are the official record of the teleconference

Dispute of Teleconference Minutes

- An applicant requesting additional clarification of the minutes should contact the assigned FDA point of contact
- Submit concerns about the minutes in writing to FDA within 10 calendar days of receipt of the official minutes
- Request should address issues regarding the minutes only
- If an applicant needs to discuss additional issues not addressed in the teleconference, submit a controlled correspondence or new meeting request (not a new PSG TC request), if appropriate

Canceling the Teleconference

- If a TC is canceled, a subsequent request to schedule another TC will be considered a new request
- It will be at FDA's discretion whether the TC should be canceled depending on specific circumstances
- Examples of canceling a TC may include:
  - Prospective ANDA applicant or applicant withdraws the request
  - Prospective ANDA applicant submits the ANDA
  - FDA refuses to receive the ANDA

* *If an applicant cancels a teleconference, FDA will count performance goal as met. If FDA cancels, will not count towards performance goal*

Challenge Question #1

Within what timeframe should an applicant submit a PSG teleconference request after publication of the new or revised PSG ?

A. 20 calendar days

B. 30 calendar days

C. 60 calendar days

D. 90 calendar days

Challenge Question #2

Which of the following statements is NOT true?

A. In general, FDA will issue preliminary written comments before a PSG teleconference.

B. Requests are granted as a teleconference or written response only format.

C. A pre-submission teleconference is submitted through the CDER Direct NextGen Collaboration Portal

D. Submit concerns about the minutes in writing to FDA within 10 calendar days of receipt of the official minutes

Summary

Pre-submission and Post-submission PSG Teleconferences	
New in GDUFA III?	Yes
Grant/Deny Decision Timeline	14 days
Format of the meeting *	Teleconference or Written Response Only (WRO)
Days to Conduct the Teleconference	30 days from receipt of meeting request
Typical Meeting Length (min)	60 min
Product Complexity	Applicable to both complex and non-complex
When to Request a Meeting	When applicant has commenced or completed in vivo BE studies that are different from FDA newly published PSGs (new or revision)

**If applicant requests a WRO instead of T-con, it may be granted as WRO*

PSG TC and Meetings

Event

- New or revised PSG

- New or revised recommendation related to in vivo BE study and applicant commenced or completed BE study

- Additional clarification

- Additional scientific discussion on approach different from PSG

Resources

The GDUFA III commitment letter is available at https://www.fda.gov/media/153631/download.

Draft guidance for Industry Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA (February 2023) at - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-specific-guidance-meetings-between-fda-and-anda-applicants-under-gdufa

Product-Specific Guidances for Generic Drug Development web page at https://www.fda.gov/drugs/guidances- drugs/product-specific-guidances-generic-drug-development

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