FDA U.S. FOOD & DRUG ADMINISTRATION

GDUFA III Teleconferences and Meetings

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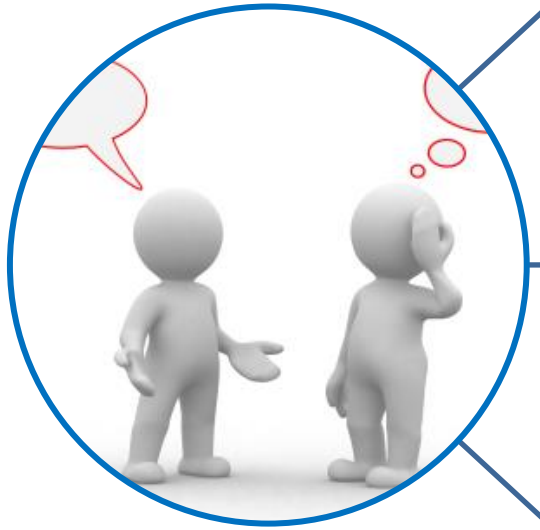
GDUFA III: What's New, What Will it Mean for Industry, and an Update on FDA's Implementation Plan

Communication to Industry: Prior to GDUFA III



Guidances

- General guidances
- **Product-specific guidance (PSG)**

Written Communi-cation

- **Controlled Correspondence**
- General Correspondence

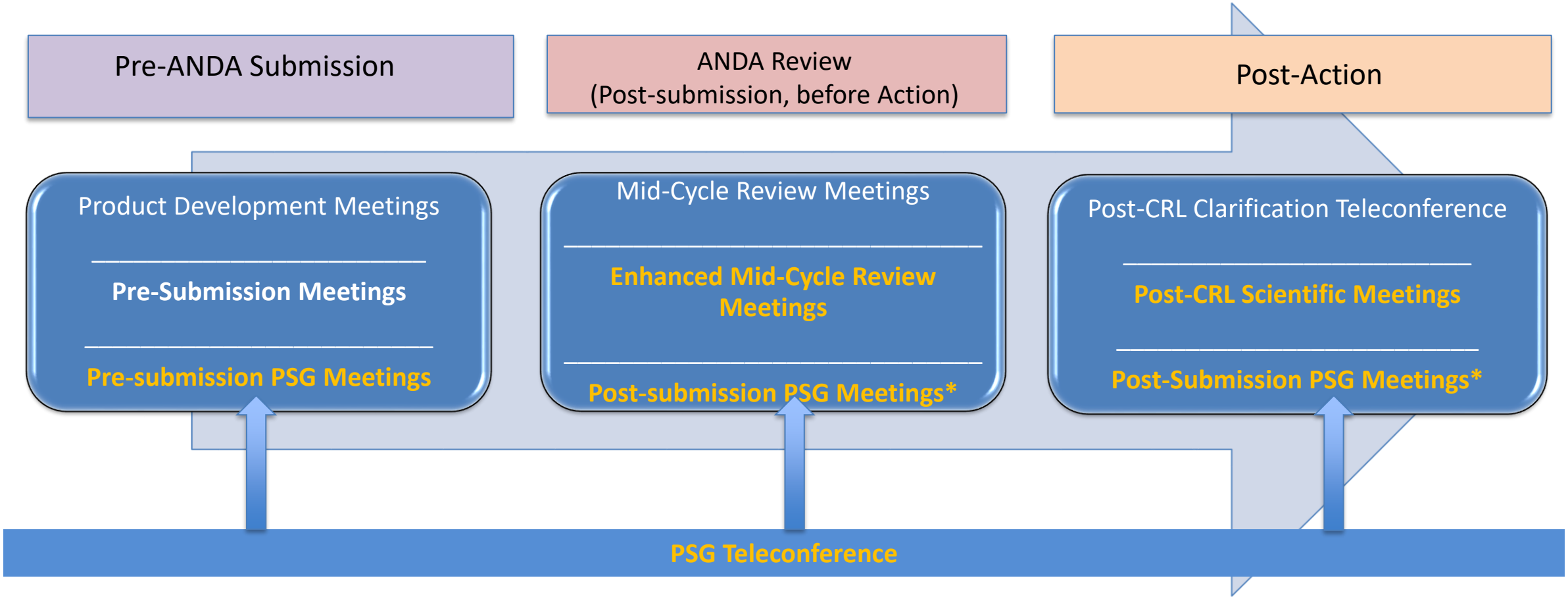
Industry Meetings

- **Product development**
- **Pre-submission**
- **Mid-review cycle meeting (new name: mid-cycle review meeting)**
- Post-CRL clarification teleconference

Started in GDUFA II:
Pre-ANDA meetings to assist prospective ANDA applicants of complex products before the submission of an ANDA to FDA.

CRL: complete response letter

GDUFA III Meetings



CR: complete response; TA: tentative approval;
AP: approval; RTR: refuse to receive

*Depend on the ANDA status, i.e., whether ANDA is under review, post-CRL or TA Action: CR, TA or AP, (during filing, RTR)

GDUFA III Teleconferences and Meetings

Clarification

Teleconference

- MCRM*
- Post-CRL Clarification Teleconference
- PSG Teleconference

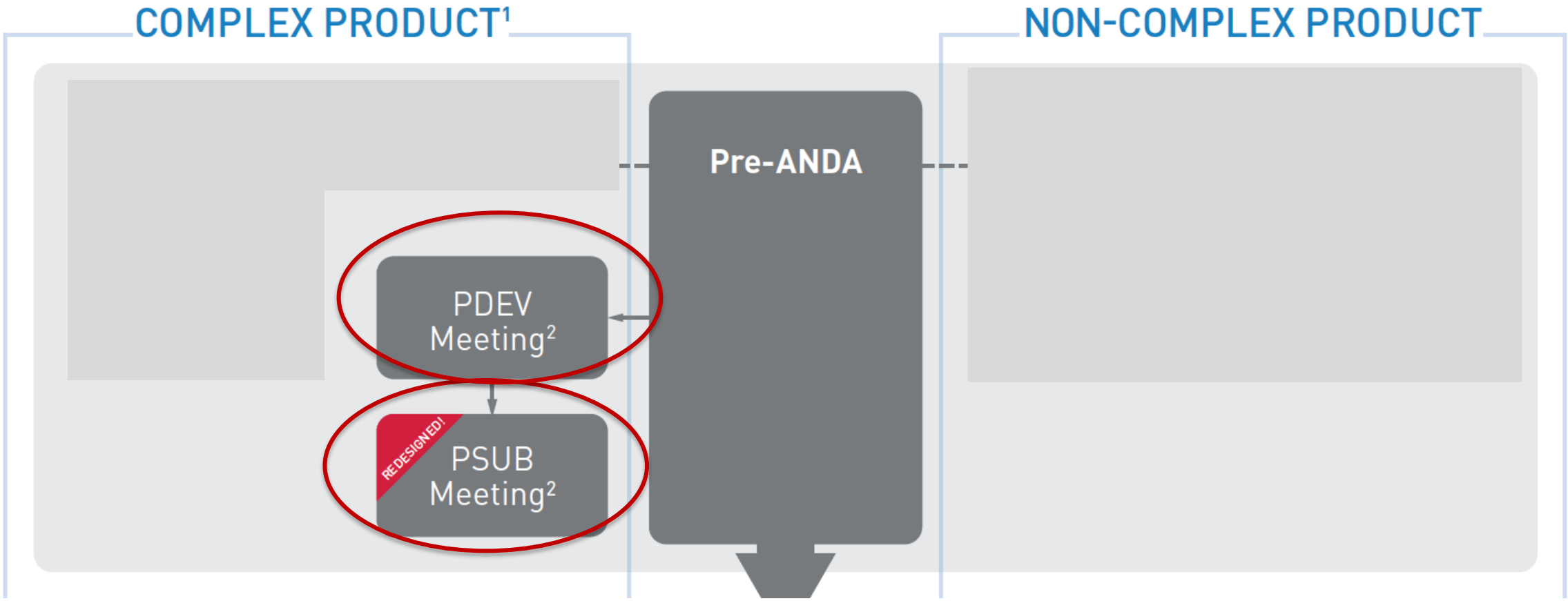
Scientific Discussion

Meeting

- Product development
- Pre-submission
- Pre-submission PSG
- Post-submission PSG
- EMCRM
- Post-CRL Scientific

MCRM: mid-cycle review meetings; EMCRM: enhanced MCRM; Post-CRL: post-complete response letter
*Meeting which is treated as a teleconference (T-con)

Pre-ANDA Stage



[1] Information on which drug products are considered complex can be found in the GDUFA III commitment letter and the CDER MAPP 5240.10 *Classifying Approved New Drug Products and Drug-device Combination Products as Complex Products for Generic Drug Development Purposes*. *Products and Drug-device Combination Products as Complex Products for Generic Drug Development Purposes*.

[2] Meeting requests for non-complex products may be granted in some situations.

Pre-ANDA Meetings

Product Development (PDEV) Meeting

- No change from GDUFA II
- Purpose: To provide a forum for a **scientific exchange** on specific issues (e.g., a proposed study design, alternative approach, additional study expectations, or questions) in which FDA will provide **targeted advice** regarding an ongoing ANDA development program

Pre-Submission (PSUB) Meeting

- Redesigned and new format/timeline in GDUFA III
- Purpose: Provide an 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, and/or methods used in product development, as well as the interrelationship of the data and information in the ANDA)
- Request the meeting around 6-8 months before ANDA submission

Pre-ANDA Stage

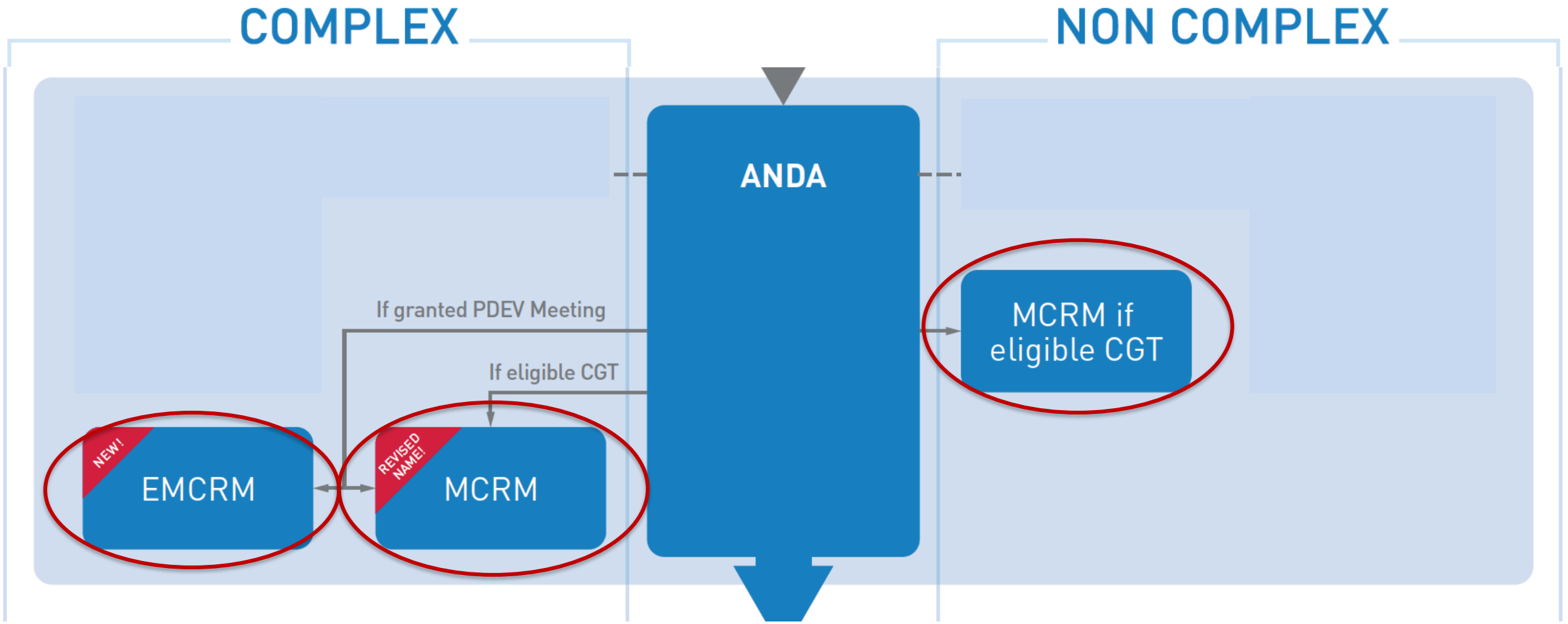
	Product Development (PDEV) Meeting	Pre-Submission (PSUB) Meeting
New in GDUFA III?	No, same as GDUFA II	No, but with modification from GDUFA II
Eligible Products	Complex; May grant non-complex	Complex with PDEV granted; May grant complex w/o PDEV or non-complex
When to Request a Meeting	No PSG, or new alternative method different from PSG recommendation (different study type)	Close to ANDA submission (6-8 months); To present unique or novel data or information that will be included in the ANDA submission
Format of the Meeting	FTF, videoconference, T-con or WR[1]	FTF or videoconference
Grant/Deny Decision Timeline	14 days*	30 days*
Days to Conduct the Meeting	120 days from meeting being granted	60 days from meeting request receipt
When to Send a Controlled Correspondence (CC) in Lieu of a Meeting Request	Clarification questions, specific technical questions, and alternative BE methods but the same type or questions outside of the scope of the meeting	This meeting will not address questions. CC will be the way if there are clarification or scientific questions.

* In the Commitment Letter

[1] FDA can provide a T-con or WR, if requested by the applicant or if FDA grants the meeting above and beyond the commitment letter

FTF: face-to-face;
BE: bioequivalence

ANDA Stage



CGT: competitive generic therapy

Mid-Cycle Review (MCRM) Meetings*

MCRM

- Revised name from GDUFA II
  - Mid-review cycle meeting (MRCM) → Mid-cycle review meeting (MCRM)
- Purpose:
  - To provide or continue to provide **targeted, robust advice** to ANDA applicants as they work to meet the standards for ANDA approval
  - Enhance the development of Complex Generic Products
  - Applicant can ask for the rationale for any deficiency identified in the mid-cycle DRL(s), and/or to ask questions related to FDA's assessment of the data or information in the ANDA

Enhanced MCRM

- New in GDUFA III
- Purpose:
  - To provide or continue to provide **targeted, robust advice** to ANDA applicants as they work to meet the standards for ANDA approval
  - Enhance the development of Complex Generic Products
  - For the applicant to ask questions related to a **proposed scientific path, potential new data or information** to address possible deficiencies identified in the mid-cycle DRL(s).
- GDUFA goal date will be extended for 60 days

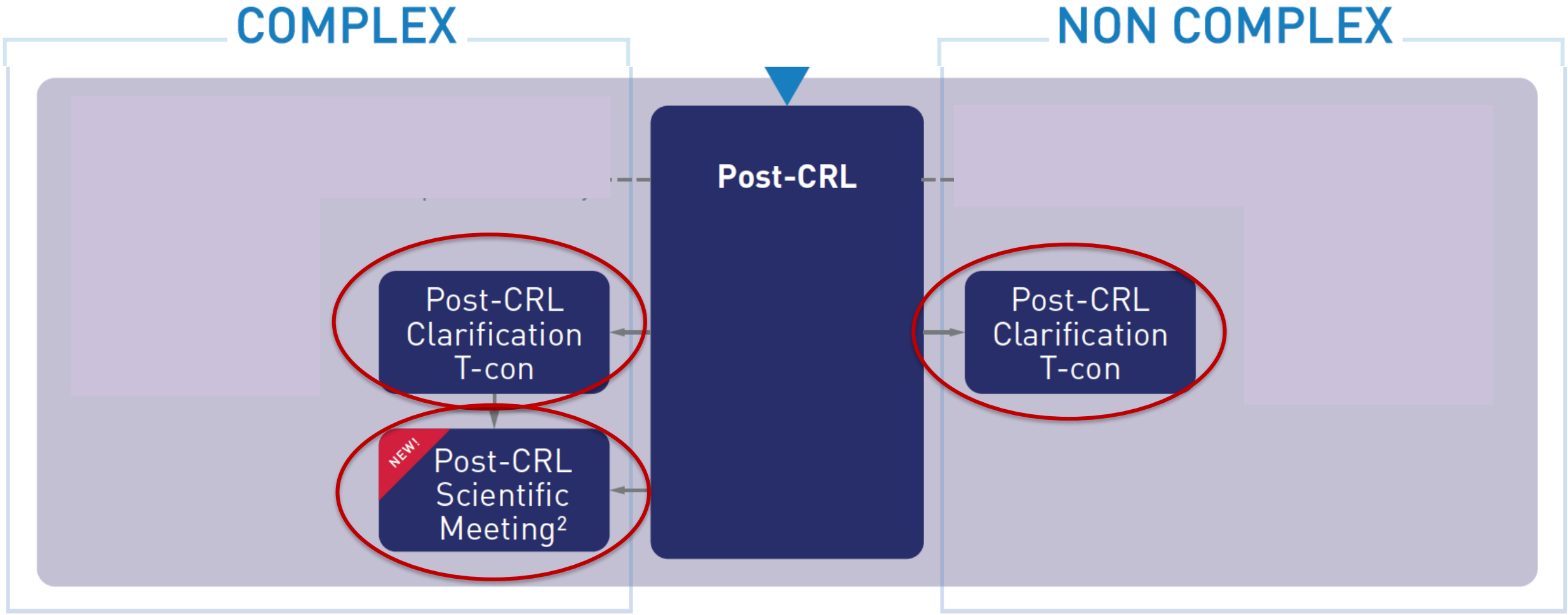
*FDA will only grant one request in the first assessment cycle (i.e., an MCRM or an EMCRM, not both)

ANDA Stage

	Mid-Cycle Review Meeting*	Enhanced Mid-cycle Review Meeting
New in GDUFA III?	No, same as GDUFA II; but applicants will need to request	Yes
Eligible Products	Complex (with PDEV meeting granted)[1]; Eligible CGTs	Complex (with PDEV meeting granted)[1]
When to Request a Meeting	Applicant seeks rationale for any possible deficiencies identified in the mid-cycle DRL(s) or has questions related to FDA's assessment of the data or information in the ANDA.	Applicant has questions about proposed scientific path, potential new data or information to address any possible deficiencies identified in the mid-cycle DRL(s).
Format of the Meeting	T-con or WR[2]	FTF, videoconference, T-con or WR[2]
Grant/Deny Decision Timeline	14 days[3]	14 days[3]
Days to Conduct the Meeting	30 days from meeting request receipt	90 days from last mid-cycle DRL issuance
When to Send a Controlled Correspondence (CC) in Lieu of a Meeting Request	Not applicable	Not applicable

[1] May grant certain complex product + PSUB only;
[2] If applicant requests a WR instead of T-con, it may be granted as WR;
[3] Applicant requests within 7 days receiving last mid-cycle DRL (i.e., the latter of the quality DRL and the bioequivalence or clinical bioequivalence DRL);
***Meeting which is treated as the T-con**

Post-Action


COMPLEX
NON COMPLEX
Post-CRL
Post-CRL Clarification T-con
NEW!
Post-CRL Scientific Meeting[2]
Post-CRL Clarification T-con

Post-CRL Meetings

Post-CRL Clarification T-con

- New grant/deny timeline in GDUFA III
  - 10 calendar days (old) → 14 calendar days
- No change in meeting format and scope
- Purpose: For applicant to seek **clarification** concerning deficiencies identified in a CRL
- Clarification questions only
  - Non-clarification will be carved out
- FDA will grant appropriate requests for teleconferences requested by applicants upon receiving first-cycle CRLs and upon receiving subsequent CRLs

Post-CRL Scientific Meeting

- New in GDUFA III
- Purpose: To provide an applicant scientific advice on possible approaches to address deficiencies identified in a CRL related to establishing equivalence
- An applicant may have a post-CRL t-con before requesting this meeting
- Applicants are eligible to request a Post-CRL Scientific Meeting even if they have not had a PDEV Meeting
- **Similar to the PDEV Meeting** (discuss complex scientific issues)

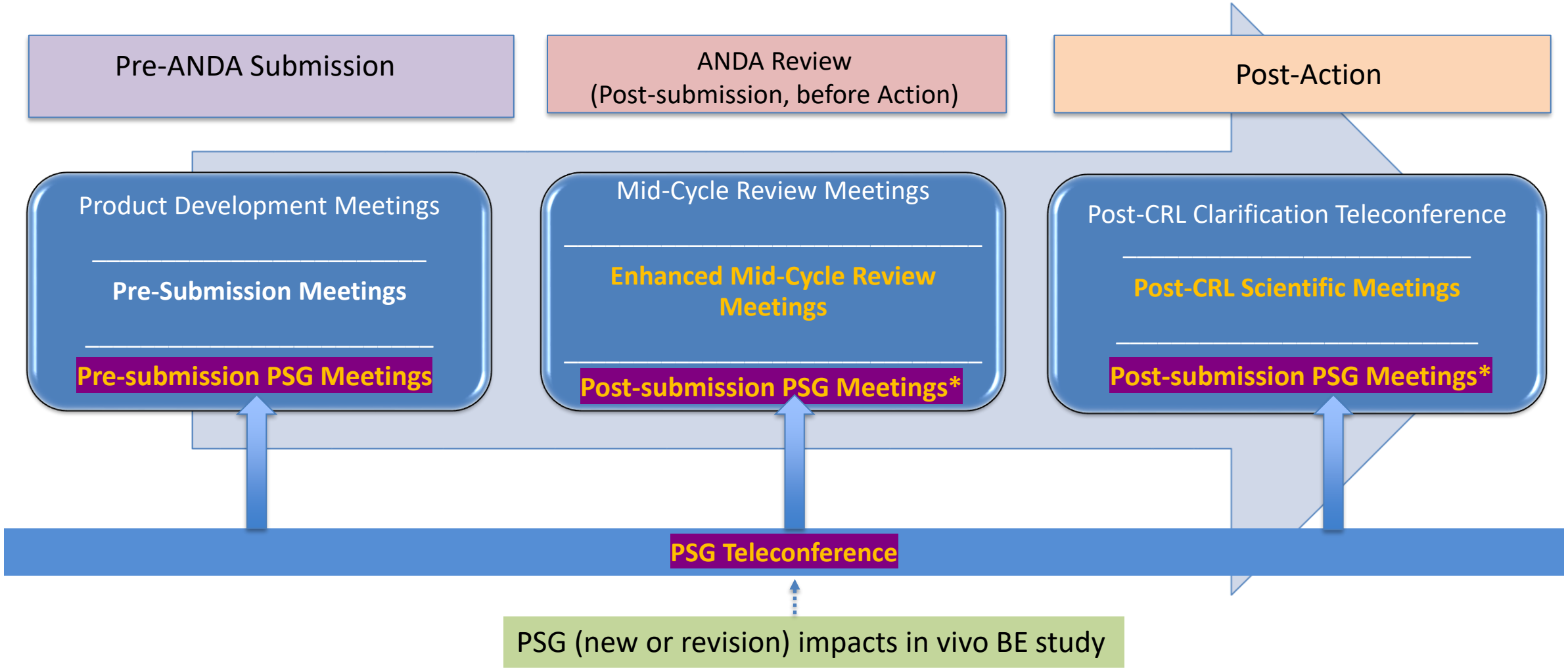
Post-Action

	Post-CRL Teleconference (Clarification Meeting)	Post-CRL Scientific Meeting
New in GDUFA III?	No, same as GDUFA II with a longer grant/deny timeline	Yes
Eligible Products	Both complex and non-complex	Complex; May grant non-complex
When to Request a Meeting	After issuance of any CRL; but submit within 10 days of CRL issuance to get 30-day goal date; Clarification questions only	Seek FDA's scientific advice on possible "new" approaches to address deficiencies identified in a CRL related to establishing equivalence (4 types)
Format of the Meeting	T-con or WR[1]	FTF, videoconference, T-con or WR[1]
Grant/Deny Decision Timeline	14 days*	14 days*
Days to Conduct the Meeting	30 days from meeting request	90 days from meeting being granted
When to Send a Controlled Correspondence (CC) in Lieu of a Meeting Request	Clarification questions submitted after 10 days of CRL issuance or questions outside of the scope of the meeting.	Clarification questions or questions outside of the scope of the meeting. Applicants can send CC after meetings if they are seeking further clarification or have new questions.

* In the Commitment Letter

[1] If applicant requests a WR instead of T-con, it may be granted as WR

PSG T-cons and Meetings



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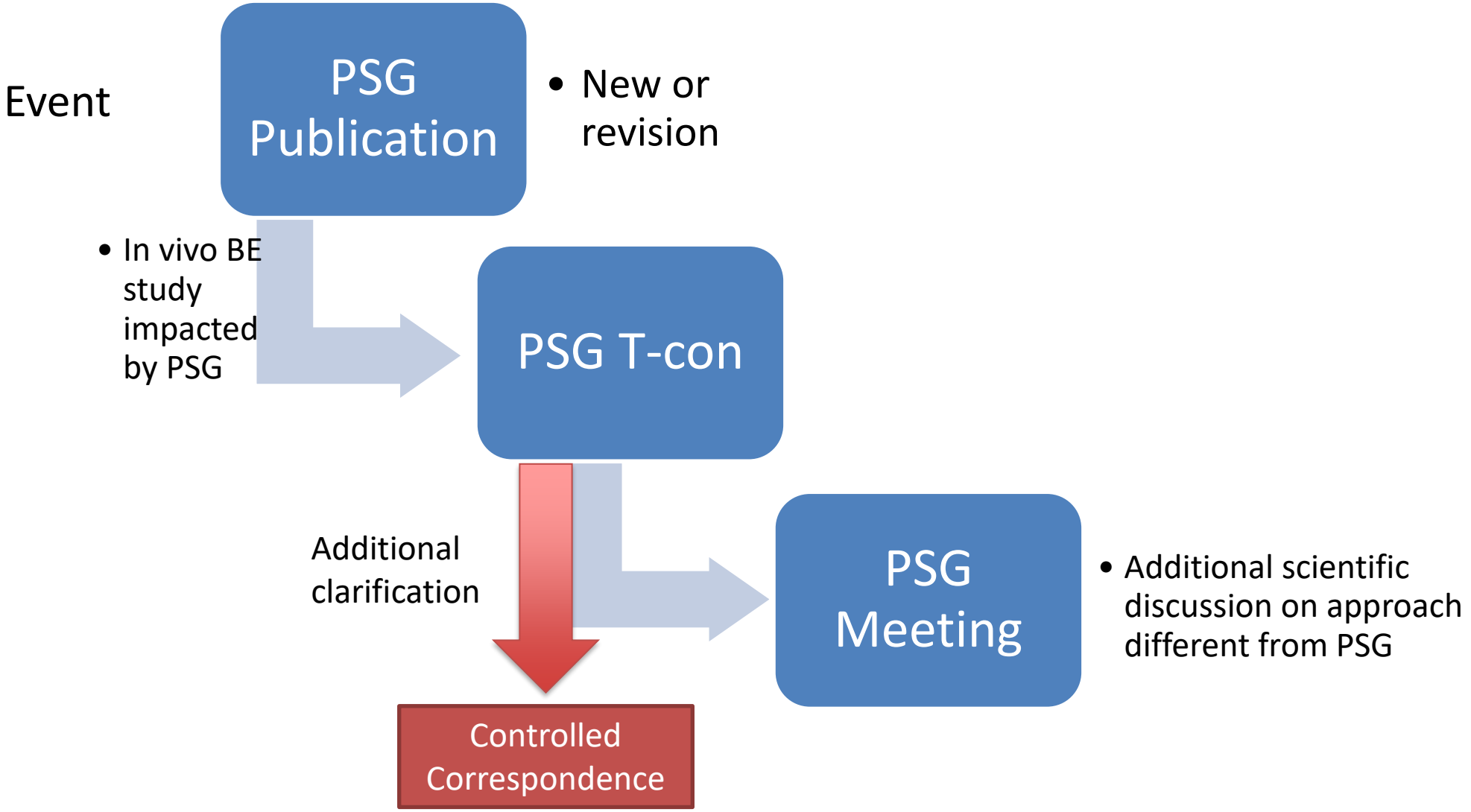
PSG T-cons and Meetings



PSG T-cons and Meetings

PSG T-con

- New in GDUFA III
- Purpose:
  - For applicant to obtain Agency feedback on the potential impact of the new or revised PSG on its development program
- If the applicant seeks further feedback from FDA after a PSG T-con, the applicant may utilize the Controlled Correspondence process or request an additional meeting

Pre-Submission PSG Meeting

- New in GDUFA III
- Purpose:
  - For applicant to have further scientific discussion **following the PSG T-con**
  - To provide a forum in which industry 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
- Request if ANDA has not been submitted yet
- Can request regardless of whether prospective applicant have had a PDEV Meeting

Post-Submission PSG Meeting

- New in GDUFA III
- Purpose:
  - For applicant to have further scientific discussion **following the PSG T-con**
  - To provide a forum in which industry 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
- Request if ANDA has been submitted
- Can request regardless of whether applicant have had a PDEV Meeting or a Post-CRL Scientific Meeting

PSG T-Cons and Meetings

	PSG T-con (Pre- or Post-Submission)	Pre-submission PSG Meeting	Post-submission PSG Meeting
New in GDUFA III?	Yes	Yes	Yes
Eligible Products	Both complex and non-complex if PSG (new or revision) impacts in vivo BE study	Both complex and non-complex if PSG (new or revision) impacts in vivo BE study; **follow up from prior PSG T-con**	
When to Request a Meeting	When applicants has already commenced an in vivo BE study that is different from FDA newly published PSGs (new or revision)	Following PSG T-con, this meeting can be requested for further scientific discussion	
Format of the Meeting	T-con or WR[1]	FTF, videoconference, T-con or WR[2]	
Grant/Deny Decision Timeline	(14 days)	14 days*	
Days to Conduct the Meeting	30 days from meeting request receipt	120 days from meeting request receipt	90 days from meeting request receipt
When to Send a Controlled Correspondence in Lieu of a Meeting Request	Seek further feedback from the FDA after a PSG T-con; Clarification questions or questions outside of the scope of the meeting	Clarification questions or questions outside of the scope of the meeting. Applicants can send CC after meetings if they are seeking further clarification or have new questions.	

* In the Commitment Letter

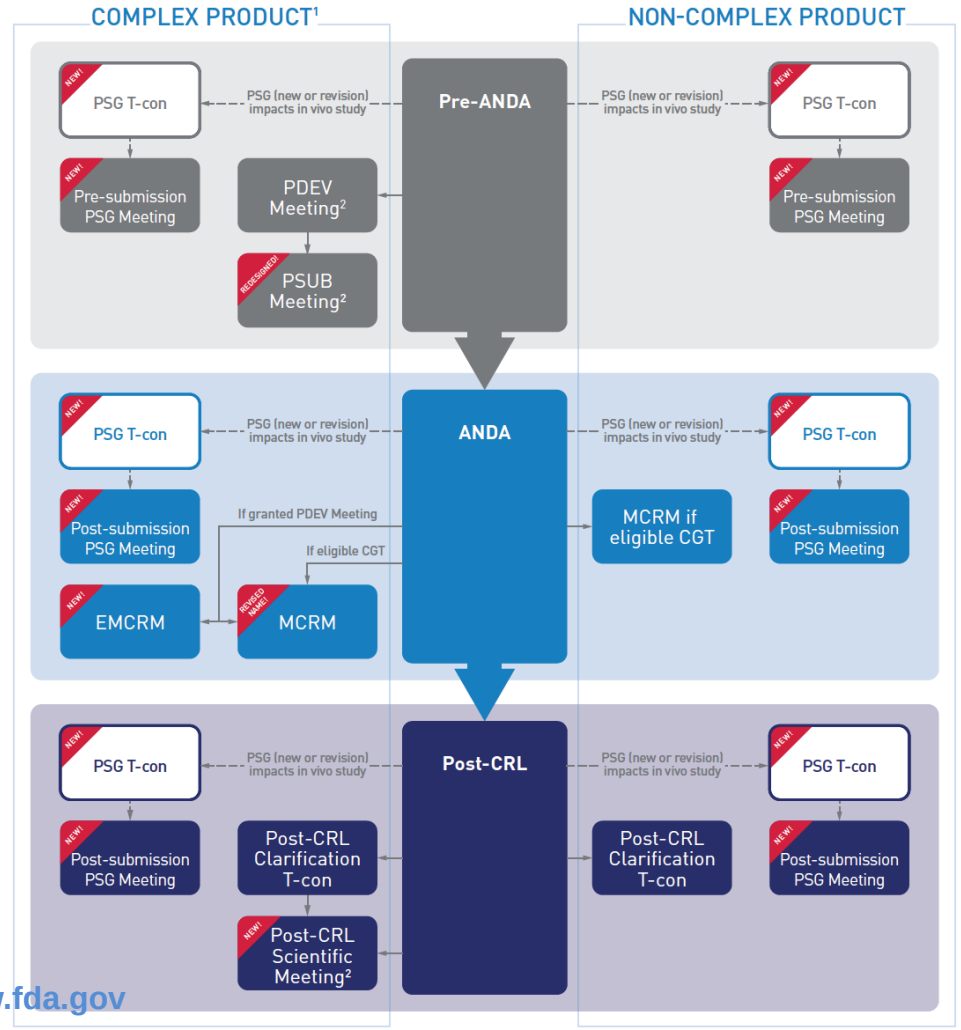
[1] If applicant requests a WR instead of T-con, it may be granted as WR

[2] FDA can provide a T-con or WR, if requested by the applicant or if FDA grants the meeting above and beyond the commitment letter

GDUFA III T-Con and Meeting Infographic

GDUFA III Commitment Letter | Summary of T-cons & Meetings

Changes with GDUFA III on and after October 1, 2022. This infographic shows a high-level overview of various T-cons and meetings including new and redesigned ones based on ANDA stage and drug product complexity.



www.fda.gov

Pre-ANDA

	"Pre-submission" PSG T-Con NEW!	Pre-submission PSG Meeting NEW!	PDEV Meeting	PSUB Meeting REDESIGNED!
Eligible Products	Complex and non-complex if PSG (new or revision) impacts in vivo BE study	Complex and non-complex if PSG (new or revision) impacts in vivo BE study	Complex[7]	Complex with PDEV meeting[8]
When to Request a Meeting	When a new or revised PSG is published and a prospective applicant has already commenced an in vivo BE study (i.e., the study protocol has been signed by the study sponsor and/or CRO)	Following PSG T-con, meeting can be requested to discuss scientific rationale for an approach other than the approach recommended in the PSG	No PSG, or new alternative BE method different from PSG recommendation	To present unique or novel data or information that will be included in the ANDA submission
Format of the Meeting	T-Con[3]	FTF[5] or VC[6]	FTF[5] or VC[6]	FTF[5] or VC
Grant/Deny Decision Timeline	14 days	14 days	14 days	30 days
Days to Conduct the Meeting	30 days from meeting request receipt	120 days from meeting request receipt	120 days from meeting being granted	60 days from meeting request receipt
When to Send CC[4] in Lieu of a Meeting Request	When a CC could adequately address the prospective applicant's questions or when the prospective applicant's clarification or scientific questions are outside of the scope of the meeting type In addition, applicants can send CC after meetings if they are seeking further clarification or have new questions			

ANDA

	"Post-submission" PSG T-Con NEW!	Post-submission PSG Meeting NEW!	MCRM REVISED NAME!	EMCRM NEW!
Eligible Products	Complex and non-complex if PSG (new or revision) impacts in vivo BE study	Complex and non-complex if PSG (new or revision) impacts in vivo BE study	Complex with PDEV meeting; CGTs	Complex with PDEV meeting
When to Request a Meeting	When a new or revised PSG is published and an applicant has already commenced an in vivo BE study (i.e., the study protocol has been signed by the study sponsor and/or CRO)	Following PSG T-con, meeting can be requested to discuss scientific rationale for an approach other than the approach recommended in the PSG	Applicant has questions about the rationale for any deficiency identified in the mid-cycle DRL[s], and/or clarification questions related to FDA's assessment of the data or information in the ANDA[9]	Applicant has questions related to a proposed scientific path to address possible deficiencies identified in the mid-cycle DRL[s] and/or questions about potential new data or information to address any possible deficiencies identified in the mid-cycle DRL[s][9]
Format of the Meeting	T-con[3]	FTF[5] or VC[6]	T-con[3]	FTF[5] or VC[6]
Grant/Deny Decision Timeline	14 days	14 days	14 days	14 days
Days to Conduct the Meeting	30 days from meeting request receipt	90 days from meeting request receipt	30 days from meeting request receipt	90 days from last mid-cycle DRL issuance
When to send CC[4] After Meeting	If the applicant seeks further feedback from FDA following the PSG T-con	Not Applicable	Not Applicable	Not Applicable

Post-CRL

	"Post-submission" PSG T-Con NEW!	Post-submission PSG Meeting NEW!	Post-CRL Clarification T-Con	Post-CRL Scientific Meeting NEW!
Eligible Products	Complex and non-complex if PSG (new or revision) impacts in vivo BE study	Complex and non-complex if PSG (new or revision) impacts in vivo BE study	Complex and non-complex	Complex[10]
When to Request a Meeting	When a new or revised PSG is published and an applicant has already commenced an in vivo BE study (i.e., the study protocol has been signed by the study sponsor and/or CRO)	Following PSG T-con, meeting can be requested to discuss scientific rationale for an approach other than the approach recommended in the PSG	Within 10 days of CRL issuance to get 30-day goal date; to seek clarification concerning deficiencies identified in a CRL	Seek FDA's scientific advice on possible approaches to address deficiencies identified in a CRL related to establishing equivalence (must discuss at least one of the 4 types outlined in section IV.C.1.a of the GDUFA III Commitment Letter)
Format of the Meeting	T-con[3]	FTF[5] or VC[6]	T-con[3]	FTF[5] or VC[6]
Grant/Deny Decision Timeline	14 days	14 days	14 days	14 days
Days to Conduct the Meeting	30 days from meeting request receipt	90 days from meeting request receipt	30 days from meeting request receipt	90 days from meeting being granted
When to send CC[4] In Lieu of a Meeting Request	When a CC could adequately address the applicant's questions or when the applicant's clarification or scientific questions are outside of the scope of the meeting type In addition, applicants can send CC after meetings if they are seeking further clarification or have new questions			

General Notes:

- FDA may grant meetings to applicants in situations beyond those described in the GDUFA III commitment letter at its discretion, and in doing so generally considers the workload and availability of staff and anticipated value to the ANDA assessment process.
- Days means calendar days in the tables above.

[1] Information on which drug products are considered complex can be found in the GDUFA III commitment letter and the CDER MAPP 5240.10 *Classifying Approved New Drug Products and Drug-device Combination Products as Complex Products for Generic Drug Development Purposes.*

[2] Meeting requests for non-complex products may be granted in some situations. See Footnotes 7, 8 and 10.

[3] WR can be provided if requested or agreed to by the applicant.

[4] FDA's goals are to respond to Level I CC within 60 days and Level II CC within 120 days.

[5] At this time FDA is hosting virtual meetings rather than in-person meetings with industry due to the COVID-19 public health emergency.

[6] FDA may provide a T-con or WR, if requested by the applicant or if the meeting is granted at FDA's discretion.

[7] A PDEV meeting may be granted for a non-complex generic product if, in FDA's judgment, the prospective applicant submits a complete meeting package, a controlled correspondence would not adequately address the prospective applicant's questions, and the meeting would significantly improve ANDA assessment efficiency.

[8] A PSUB meeting may be granted for applicants who were not granted a PDEV meeting for the same complex generic product or for a non-complex generic product if FDA believes in its sole discretion that the PSUB meeting would improve assessment efficiency.

[9] Applicants have 7 days from receipt of the last mid-cycle DRL to submit a request for an MCRM or EMCRM.

[10] A post-CRL scientific meeting may be granted for a non-complex generic product if in FDA's judgement the request raises issues that are best addressed via this meeting process and cannot be adequately addressed through CC.

Abbreviation	Meaning
ANDA	Abbreviated New Drug Application
BE	Bioequivalence
CC	Controlled Correspondence
CGT	Competitive Generic Therapy
CRL	Complete Response Letter
DRL	Discipline Review Letter
EMCRM	Enhanced Mid-Cycle Review Meeting
FTF	Face-to-Face
GDUFA	Generic Drug User Fee Amendments
MCRM	Mid-Cycle Review Meeting
PDEV	Product Development
PSG	Product-Specific Guidance
PSUB	Pre-Submission
T-con	Teleconference
VC	Videoconference
WR	Written Response

https://www.fda.gov/media/162239/download

Product-Specific Guidance in GDUFA III

In addition to PSG T-con and meetings, two major changes related to PSG in GDUFA III:

- **New goal dates for newly approved complex products**
  - For Complex Products approved in new drug applications (NDAs) on or after October 1, 2022, a PSG will be issued for 50% of such NDA products within 2 years after the date of NDA approval, and for 75% of such NDA products within 3 years after the date of NDA approval.
- **Upcoming PSG forecast website will include all products**
  - FDA will provide on its website information related to upcoming new and revised PSG, including the projected date of PSG publication, which may be subject to change.
  - When FDA becomes aware that it will not meet the issuance date listed on the website, FDA will update the website to provide a new projected issuance date in the next scheduled update.

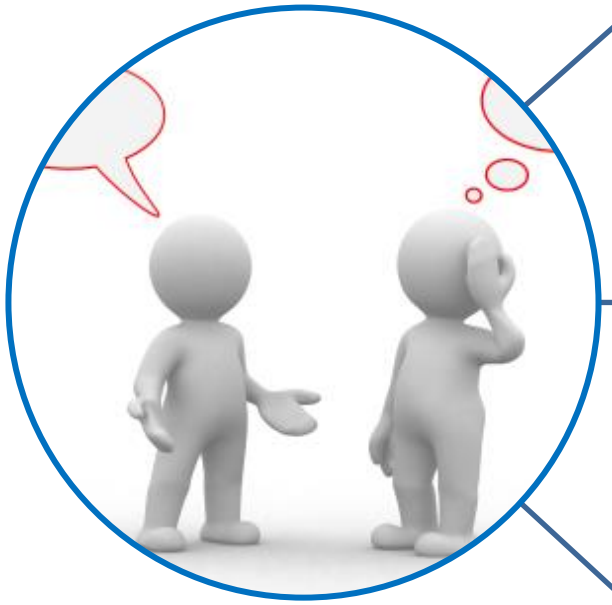
GDUFA III Commitment Letter

Controlled Correspondence in GDUFA III

- Change in terminology
  - **Level 1** vs. Standard = 60 Calendar goal days
  - **Level 2** vs. Complex = 120 Calendar goal days
- Can be submitted throughout product lifecycle
  - Prior to ANDA submission
  - *New:* Pre- or post-PSG T-con or meeting
  - *New:* Post issuance of a CRL
  - *New:* Once the application is in tentative approval or approved status
- Change in days to send clarification of ambiguity
  - Within 21 calendar days (vs. with 14 calendar days before)

GDUFA III Commitment Letter

Communication to Industry: GDUFA III



Guidances

- General guidances
- **Timely development and transparency on PSGs for all products**

Written Communi-cation

- **Controlled Correspondence to provide input throughout product life cycle**

Industry Meetings

- **More meetings under GDFUA III to provide input throughout product life cycle**
  - More meetings in different situations
  - More transparency
  - More efficient development and decisions about complex generics

Resources

- GDUFA III Commitment Letter
- MAPP 5240.10: Classifying Approved New Drug Products as Complex Products for Generic Drug Development Purposes
- GDUFA III Enhancement to the Pre-ANDA Program: https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iii-enhancements-pre-anda-program
- ANDA Assessment Program – GDUFA III Performance Goals and Program Enhancements: https://www.fda.gov/industry/generic-drug-user-fee-amendments/anda-assessment-program-gdufa-iii-performance-goals-and-program-enhancements
- GDUFA III Meeting-Related Guidances and MAPPs
  - Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA (Oct 2022)
  - Post-CRL Clarification T-con between FDA and ANDA Applicants Under GDUFA (Oct 2022)
  - Competitive Generic Therapies (Oct 2022)
  - MAPP 5220.8: Evaluating Requests for and Conducting Product Development and Pre-Submission Pre-ANDA Meetings (Oct 2022)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