U.S. FOOD & DRUG ADMINISTRATION

A New GDUFA III Meeting: Post- Complete Response Letter (CRL) Scientific Meeting

Tao Bai, Ph.D.

Senior Advisor

Office of Bioequivalence (OB), Office of Generic Drugs (OGD),
Center for Drug Evaluation & Research (CDER), FDA

SBIA Generic Drug Forum

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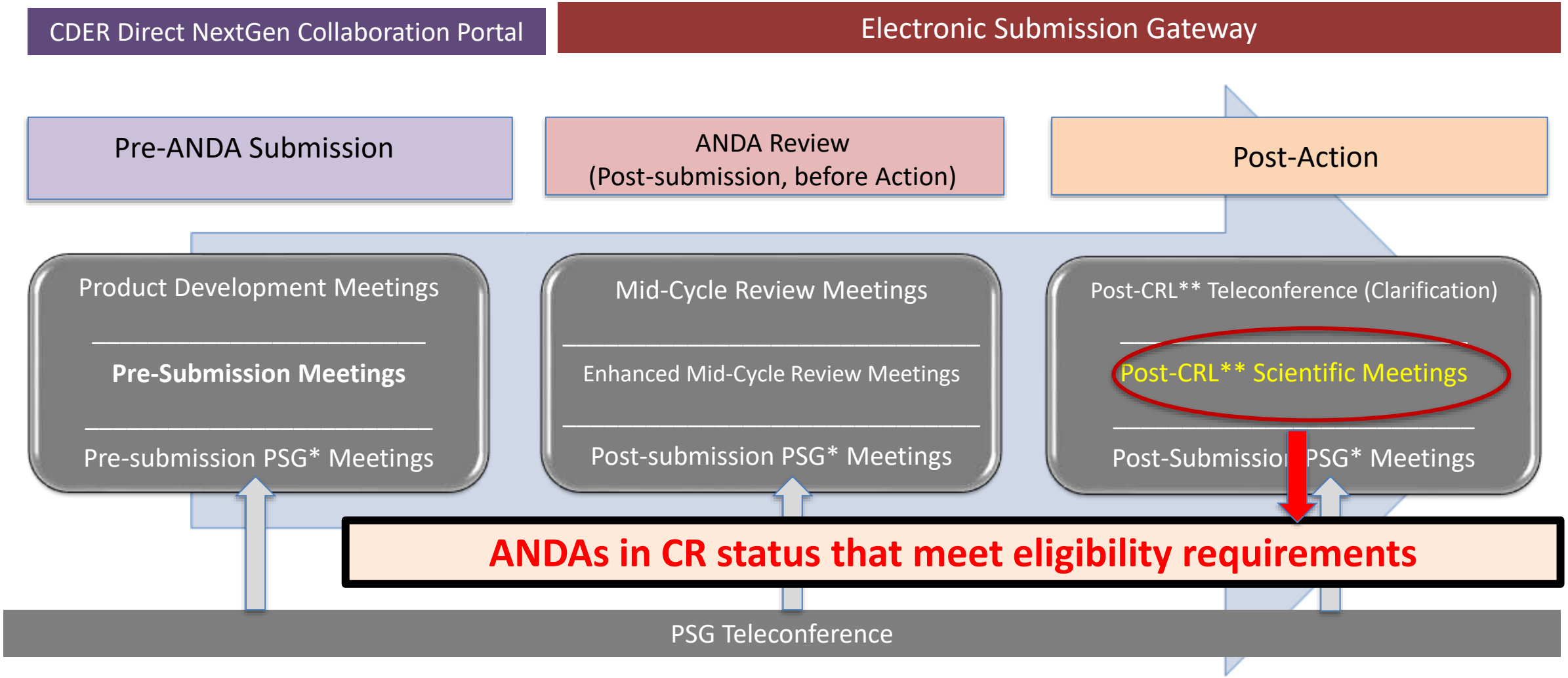
Outline

- Introduction
- Purpose
- Grant/Deny Decision Criteria
- Meeting Process and Timeline
- Challenge Question

GDUFA III Meetings



*PSG: Product Specific Guidance

**CRL: Complete Response Letter

Purpose

- *Purpose of* ***ANDA Assessment Meeting Program*** - Provide or continue to provide targeted, robust advice to ANDA applicants as they work to meet the standards for ANDA approval.

- *Purpose for* ***Post-CRL Scientific Meeting*** - Provide an applicant scientific advice on possible approaches to address deficiencies identified in a CRL related to establishing equivalence.

GDUFA III Commitment Letter

Does not have to have had a post-CRL teleconference prior to requesting this meeting

An applicant can request a Post-CRL Scientific Meeting.

Does not have to have had a Product Development Meeting

A meeting request must discuss:

- a new equivalence study needed to address the deficiencies in the design identified in the CRL
- an approach that is different from that submitted in the ANDA, e.g., a change in study type from in vivo to in vitro
- a new comparative use human factors study
- a new approach to demonstrating sameness of a complex active ingredient

and

it is a complex generic product, or in FDA's judgment the request raises issues that are best addressed via this meeting process and cannot be adequately addressed through Controlled Correspondence

FDA agreed to grant or deny the Post-CRL Scientific Meeting request within **14 days** after receipt of the request.

FDA agreed to hold the Post-CRL Scientific Meeting within **90 days** after the date the meeting is granted.

GDUFA III Commitment Letter IV. C.

Will Grant

Meet both criteria below:

- Complex generic product, and

- Relates to one or more of following four topics:
  - a new equivalence study needed to address the deficiencies in the design identified in the CRL;
  - an approach that is different from that submitted in the ANDA, e.g., a change in study type from in vivo to in vitro;
  - a new comparative use human factors study, or
  - a new approach to demonstrating sameness of a complex active ingredient

May Grant

In FDA's judgment the request raises issues that are best addressed via this meeting process and cannot be adequately addressed through Controlled Correspondence

May be Denied Scenario

A post-CRL scientific meeting request may be denied because

- The product does not meet the criteria for a complex product, or
- In FDA's judgment the request raises issues that can be adequately addressed through controlled correspondence, or
- The meeting request does not discuss one of the following as it relates to establishing equivalence:
  - a new equivalence study needed to address the deficiencies in the design identified in the CRL;
  - an approach that is different from that submitted in the ANDA, e.g., a change in study type from in vivo to in vitro;
  - a new comparative use human factors study, or
  - a new approach to demonstrating sameness of a complex active ingredient

Timeline

ANDAs in CR status that meet eligibility requirements

Grant/Deny Decision Issued to Applicant	• Within 14 days after receipt of the Meeting Request
Preliminary Responses to Applicant Questions	• Issued no later than 5 days prior to the external meeting with applicant
Meeting/Teleconference Held or Written Responses Issued	• Within 90 days after the date the meeting is granted
Meeting Minutes	• Issued within 30 days of the meeting or teleconference

If a due date falls on a weekend or federal holiday, it will be moved to the preceding business day

After Grant/Deny Decision is Made…

- **Denial Letter** –
  - Justification for the denial

- **Grant Letter** –
  - Meeting time/date, or goal date for providing written responses
  - Preliminary list of FDA attendees
  - Meeting format (i.e., in-person face-to-face, videoconference, teleconference, or written response only)

Expectations of the Meeting Package…

- The cover letter should clearly identify that it is a "*Post-Complete Response Letter Scientific Meeting Request*"
- Clearly state if it is a complex/non-complex drug product, and include any rationale or justifications for why the product meets the criteria for a complex product, if applicable
- Clearly state which of the four criteria (in the GDUFA III Commitment Letter) relating to establishing equivalence the meeting request (potential discussion) is focusing on
- Clearly state the requested format (i.e., in-person face-to-face, videoconference, teleconference, or written response only)

A Post-CRL Scientific Meeting May be Cancelled If …

- The applicant withdraws the meeting request, or
- The applicant informs FDA that its questions have been adequately answered by preliminary written comments, or
- FDA issues product-specific guidance on establishing bioequivalence to the reference listed drug (RLD), which addresses the questions in the meeting package.

Related to Preliminary Response…

- FDA intends to issue no later than 5 days prior to the meeting
- The meeting may be canceled if the applicant finds the preliminary written comments are adequate to address their questions
- If a meeting is still to be held, the applicant should provide an updated agenda with its list of questions and any proposed presentation materials, no later than 48 hours before the meeting

After the Meeting is Held…

- FDA will issue meeting minutes within 30 days of the meeting
- FDA meeting minutes are the official minutes of the meeting
- If the applicant believes there is a discrepancy in the minutes, they should submit their concerns in writing within 10 calendar days of the receipt of the official meeting minutes

References

- Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA Guidance for Industry (October 2022) (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-anda-applicants-complex-products-under-gdufa-guidance-industry)

- FDA GDUFA III Reauthorization Page https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iii-reauthorization

Upcoming SBIA Webinar on Post-CRL Scientific Meeting

- **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

https://www.fda.gov/drugs/news-events-human-drugs/deep-dive-gdufa-iii-scientific-meetings-05152023

Challenge Question

Is the statement below true or false?

A post-CRL scientific meeting request can only be submitted after first submitting a post-CRL teleconference to the agency.

- True
- False